APPENDIX I
## 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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Center FTEs</th>
<th>Total Center Dollars</th>
<th>Total Field FTEs</th>
<th>Total Field Dollars</th>
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<tr>
<td>1993</td>
<td>98</td>
<td>$6,023,000.00</td>
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<td>$4,200,000.00</td>
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<td>1994</td>
<td>105</td>
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<td>1995</td>
<td>98</td>
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<td>1996</td>
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<td>1998</td>
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<td>1999</td>
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<td>83</td>
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<td>2001</td>
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<td>$6,864,000.00</td>
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<td>$4,800,000.00</td>
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<td>Est. 2002</td>
<td>70</td>
<td>$6,647,543.00</td>
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<td>$5,900,000.00</td>
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*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.
APPENDIX II
## Examples of Pending ONPLDS Petitions Submitted from 1991-2002
### Appendix II

<table>
<thead>
<tr>
<th>Docket #</th>
<th>Petition Date</th>
<th>Petitioner</th>
<th>Summary</th>
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<tbody>
<tr>
<td>91P-0050</td>
<td>Feb. 11, 1991</td>
<td>Michael Foods, Inc.</td>
<td>Requests that FDA amend the Standard of Identity for liquid eggs to permit ultra pasteurized liquid whole eggs.</td>
</tr>
<tr>
<td>91P-0051</td>
<td>Feb. 13, 1991</td>
<td>Producers and distributors of cooking wine represented by Olsson, Frank &amp; Weeda.</td>
<td>Requests that FDA propose and adopt a common or usual name regulation to codify the name “cooking wine.”</td>
</tr>
<tr>
<td>91P-0297</td>
<td>Mar. 29, 1991</td>
<td>Nutrients Incorporated</td>
<td>Requests that use of the term “mineral salts” be permitted.</td>
</tr>
<tr>
<td>91P-0234</td>
<td>Jun. 17, 1991</td>
<td>Lois M. Meyer (FDA Employee)</td>
<td>Requests that FDA amend regulations for food labeling print size and color contrast to improve readability.</td>
</tr>
<tr>
<td>93P-0070</td>
<td>Feb. 10, 1993</td>
<td>Infant Formula Council</td>
<td>Requests that FDA establish an exemption from print size requirements for all infant formula.</td>
</tr>
<tr>
<td>93P-0227</td>
<td>Jun. 25, 1993</td>
<td>Center for Science in the Public Interest</td>
<td>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.</td>
</tr>
<tr>
<td>93P-0296</td>
<td>Aug. 4, 1993</td>
<td>National Soft Drink Association</td>
<td>Requests that FDA amend the regulation governing the placement of soft drink identity statements when the product is identified by a well-known trademark.</td>
</tr>
<tr>
<td>93P-0486</td>
<td>Dec. 15, 1993</td>
<td>Wine Institute</td>
<td>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.</td>
</tr>
<tr>
<td>94P-0029</td>
<td>Jan. 26, 1994</td>
<td>Calorie Control Council</td>
<td>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.</td>
</tr>
<tr>
<td>Case No.</td>
<td>Date</td>
<td>Requestor</td>
<td>Request</td>
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<tr>
<td>94P-0079</td>
<td>Feb. 4, 1994</td>
<td>National Soft Drink Association</td>
<td>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.</td>
</tr>
<tr>
<td>94P-0187</td>
<td>May 20, 1994</td>
<td>Food Marketing Institute and National Grocers Association</td>
<td>Requests that FDA amend its ingredient labeling requirements applicable to foods prepared and packaged at retail stores.</td>
</tr>
<tr>
<td>94P-0293</td>
<td>Aug. 2, 1994</td>
<td>The Sugar Association, Inc.</td>
<td>Requests that FDA issue regulations to provide consistency in the use of the term “sugar” and “sugars” on food labels and labeling.</td>
</tr>
<tr>
<td>94P-0413</td>
<td>Nov. 14, 1994</td>
<td>National Pasta Association and the Millers’ National Federation</td>
<td>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.</td>
</tr>
<tr>
<td>95P-0099</td>
<td>Apr. 4, 1995</td>
<td>Calorie Control Council</td>
<td>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.</td>
</tr>
<tr>
<td>95P-0112</td>
<td>Apr. 25, 1995</td>
<td>Cancer Prevention Coalition</td>
<td>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.”</td>
</tr>
<tr>
<td>95P-0241</td>
<td>Jul. 27, 1995</td>
<td>American Bakers Association</td>
<td>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.</td>
</tr>
<tr>
<td>95P-0246</td>
<td>Aug. 2, 1995</td>
<td>Center for Science in the Public Interest</td>
<td>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.</td>
</tr>
<tr>
<td>95P-0392</td>
<td>Oct. 31, 1995</td>
<td>John Marion Ellis, M.D.</td>
<td>Requests that FDA issue an order to require fortification of foods with vitamin B6.</td>
</tr>
<tr>
<td>96P-0111</td>
<td>Apr. 4, 1996</td>
<td>American Cocoa Research Institute</td>
<td>Requests that FDA amend the nutrition labeling regulations to communicate the fact that stearic acid does not affect blood cholesterol.</td>
</tr>
<tr>
<td>Request Number</td>
<td>Date</td>
<td>Requestor</td>
<td>Request</td>
</tr>
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<tr>
<td>96P-1043</td>
<td>Apr. 29, 1996</td>
<td>Calorie Control Council</td>
<td>Requests that FDA amend the food labeling regulations to permit the removal or reduction of an ingredient of standardized foods.</td>
</tr>
<tr>
<td>96P-0230</td>
<td>Jun. 26, 1996</td>
<td>Purac America, Inc.</td>
<td>Requests that FDA amend the regulations for designating food ingredients for black olives.</td>
</tr>
<tr>
<td>96P-0464</td>
<td>Nov. 27, 1996</td>
<td>Center for Science in the Public Interest</td>
<td>Requests that FDA prevent the unapproved use of the term “energy” on the labels of food packages.</td>
</tr>
<tr>
<td>97P-0043</td>
<td>Feb. 3, 1997</td>
<td>American Bakers Association</td>
<td>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.</td>
</tr>
<tr>
<td>97P-0056</td>
<td>Feb. 10, 1997</td>
<td>Calorie Control Council</td>
<td>Requests that FDA permits a caloric value of not more than 2 calories per gram for soluble fiber in food labeling.</td>
</tr>
<tr>
<td>97P-0078</td>
<td>Feb. 28, 1997</td>
<td>Soyfoods Association of America</td>
<td>Requests that FDA issue a regulation recognizing “soymilk” as the established common or usual name to be used in labels and labeling.</td>
</tr>
<tr>
<td>97P-0130</td>
<td>Mar. 26, 1997</td>
<td>Center for Science in the Public Interest</td>
<td>Requests that FDA issue regulations to require percentage ingredient labeling for characterizing ingredients in foods.</td>
</tr>
<tr>
<td>97P-0142</td>
<td>Mar. 31, 1997</td>
<td>International Jelly &amp; Preserve Association</td>
<td>Requests that FDA repeal the standards of identity for artificially sweetened jelly and preserves.</td>
</tr>
<tr>
<td>97P-0187</td>
<td>May 17, 1997</td>
<td>Nabisco, Inc.</td>
<td>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.</td>
</tr>
<tr>
<td>97P-0329</td>
<td>Jul. 31, 1997</td>
<td>Center for Science in the Public Interest</td>
<td>Requests that FDA require quantitative disclosure of caffeine content.</td>
</tr>
<tr>
<td>97P-0498</td>
<td>Jul. 31, 1997</td>
<td>The University of Vermont</td>
<td>Requests that FDA require quantitative labeling of caffeine on food and beverage containers.</td>
</tr>
<tr>
<td>97P-0360</td>
<td>Aug. 16, 1997</td>
<td>Lt. Colonel Lighter</td>
<td>Requests that FDA require all packaged food to use an “open dating” system.</td>
</tr>
<tr>
<td>98P-0005</td>
<td>Dec. 15, 1997</td>
<td>International Specialty Products</td>
<td>Requests that FDA exempt drugs and food supplements containing carbonyl iron from special packaging and labeling requirements.</td>
</tr>
<tr>
<td>98P-0047</td>
<td>Jan. 13, 1998</td>
<td>The Association for Dressings &amp; Sauces</td>
<td>Requests that FDA repeal the standard of identity for French dressing and revise the standards of identity for mayonnaise and salad dressing.</td>
</tr>
<tr>
<td>Petition</td>
<td>Date</td>
<td>Requesting Organization</td>
<td>Request</td>
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<tr>
<td>98P-0360</td>
<td>May 21, 1998</td>
<td>National Food Processors Association</td>
<td>Requests that FDA remove the labeling requirements for irradiated food.</td>
</tr>
<tr>
<td>98P-0418</td>
<td>Jun. 10, 1998</td>
<td>Center for Science in the Public Interest</td>
<td>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.</td>
</tr>
<tr>
<td>98P-0696</td>
<td>Aug. 10, 1998</td>
<td>Mr. Kenneth B. Lerman</td>
<td>Requests that FDA disclose all ingredients on food labels and labeling. If any of the ingredients are dead animals, the label should then indicate &quot;Non-Vegetarian&quot; at the end of the ingredient list.</td>
</tr>
<tr>
<td>98P-0724</td>
<td>Aug. 24, 1998</td>
<td>Center for Science in the Public Interest</td>
<td>Requests that FDA take a number of actions relating to the safety and labeling of cochineal extract and carmine color additives.</td>
</tr>
<tr>
<td>99P-0301</td>
<td>Feb. 22, 1999</td>
<td>The Procter &amp; Gamble Co., Bestfoods and Hunt-Wesson, Inc.</td>
<td>Requests that FDA amend peanut spread regulations to remove the requirements for added vitamins, minerals and protein.</td>
</tr>
<tr>
<td>99P-0795</td>
<td>Mar. 30, 1999</td>
<td>Natural Resources Defense Council</td>
<td>Requests that FDA amend its regulations and policies on bottled water.</td>
</tr>
<tr>
<td>99P-2630</td>
<td>Aug. 3, 1999</td>
<td>Center for Science in the Public Interest</td>
<td>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.</td>
</tr>
<tr>
<td>99P-4208</td>
<td>Sep. 27, 1999</td>
<td>Center for Science in the Public Interest</td>
<td>Requests that FDA revise the labeling requirements for foods that contain sorbitol.</td>
</tr>
<tr>
<td>99P-5106</td>
<td>Nov. 17, 1999</td>
<td>Vegetarian Legal Action Network</td>
<td>Requests that FDA amend its regulations to require manufacturers to disclose the sources of natural flavors.</td>
</tr>
<tr>
<td>99P-5198</td>
<td>Dec. 2, 1999</td>
<td>American Dairy Products Institute</td>
<td>Requests that FDA amend the definition of milk to include fluid ultrafiltered milk.</td>
</tr>
<tr>
<td>00P-0425</td>
<td>Feb. 3, 2000</td>
<td>Mead-Johnson</td>
<td>Requests that FDA revise labeling and placement requirements for low-iron formulas.</td>
</tr>
<tr>
<td>00P-1211</td>
<td>Mar. 22, 2000</td>
<td>The Center for Food Safety</td>
<td>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.</td>
</tr>
<tr>
<td>Request ID</td>
<td>Date</td>
<td>Org.</td>
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</tr>
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<tr>
<td>00P-1322</td>
<td>May 30, 2000</td>
<td>9 Attorneys General</td>
<td>Requests that FDA amend its rules and regulations regarding the labeling and manufacture of foods containing allergenic substances.</td>
</tr>
<tr>
<td>00P-1491</td>
<td>Aug. 30, 2000</td>
<td>Kraft Foods</td>
<td>Requests that FDA initiate rulemaking to amend the standard of identity for parmesan cheese.</td>
</tr>
<tr>
<td>00P-1572</td>
<td>Oct. 18, 2000</td>
<td>State of Alaska</td>
<td>Requests that FDA adopt a standard of identity for bottled water based on the source for glacier water and glacier-fed water.</td>
</tr>
<tr>
<td>00P-1680</td>
<td>Dec. 21, 2000</td>
<td>Protein Technologies International</td>
<td>Requests that FDA amend the definition and standard of identity for Parmesan cheese.</td>
</tr>
<tr>
<td>01P-0190</td>
<td>Apr. 23, 2001</td>
<td>Judy Zapka and the Center for Food Safety</td>
<td>Requests that FDA amend its labeling regulations to indicate that bottled diet Coca Cola and fountain Coca Cola contain different sweeteners.</td>
</tr>
<tr>
<td>01P-0290</td>
<td>Jul. 2, 2001 / Jan. 28, 2003</td>
<td>Hodgson Mill</td>
<td>Requests that FDA issue a definition for the term “stone ground” as applied to wheat flour. Seeks reconsideration of this request.</td>
</tr>
<tr>
<td>01P-0320</td>
<td>Jul. 26, 2001</td>
<td>Center for Science in the Public Interest</td>
<td>Requests that FDA propose rulemaking to establish format requirements for ingredient lists.</td>
</tr>
<tr>
<td>01P-0406</td>
<td>Sep. 14, 2001</td>
<td>The International Bottled Water Association</td>
<td>Requests that FDA require producers of bottled water to include telephone contact information on the labels of bottled water.</td>
</tr>
<tr>
<td>00P-1322/CP2</td>
<td>Oct. 4, 2001</td>
<td>Center for Science in the Public Interest</td>
<td>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.</td>
</tr>
<tr>
<td>00P-1439</td>
<td>Oct. 10, 2001</td>
<td>Iceberg Industries Corporation</td>
<td>Requests that FDA amend the standard for Iceberg Water.</td>
</tr>
<tr>
<td>02P-0122</td>
<td>Mar. 22, 2002</td>
<td>Center for Science in the Public Interest</td>
<td>Requests that FDA adopt recommendations for functional foods contained in a July 2000 GAO report.</td>
</tr>
<tr>
<td>03P-0041</td>
<td>Jan. 31, 2003</td>
<td>Bunker Hill Cheese Co.</td>
<td>Requests that FDA permit use of the term “yogurt cheese” as a common or usual name.</td>
</tr>
<tr>
<td>2003Q-0401</td>
<td>June 23, 2003</td>
<td>Wellness Lifestyles, Inc. D/B/A American Longevity and Life Extension Foundations Buyers Club, Inc.</td>
<td>Requests FDA to permit a claim that consumption of omega-3 fatty acids may reduce the risk of coronary heart disease.</td>
</tr>
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</table>
APPENDIX III
## Examples of Pending ONPLDS Rulemaking Activities

### Appendix III

<table>
<thead>
<tr>
<th>Federal Register Citation &amp; Docket</th>
<th>Date</th>
<th>Action</th>
<th>Summary</th>
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<tr>
<td>58 FR 2950</td>
<td>Jan. 6, 1993</td>
<td>Advance Notice of Proposed Rulemaking</td>
<td>FDA intends to require that canned tuna with the ingredient vegetable broth use the term &quot;includes soybeans&quot; 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 sweeteners in soft drinks.</td>
</tr>
<tr>
<td>Docket # 90N-361M*</td>
<td></td>
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</tr>
<tr>
<td>60 FR 67492</td>
<td>Dec. 29, 1995</td>
<td>Advance Notice of Proposed Rulemaking</td>
<td>FDA intends to review its regulations pertaining to identity, quality, and fill of containers for standardized foods and its common or usual name regulations for nonstandardized foods.</td>
</tr>
<tr>
<td>Docket # 95N-0294</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>61 FR 29701</td>
<td>Jun. 12, 1996</td>
<td>Advance Notice of Proposed Rulemaking</td>
<td>FDA intends to review food labeling regulations pertaining to the exemption for soft drinks from requirements for type size; requirements for “statements of identity” and flavor labeling; requirements for labeling food additives; and its infant formula regulations to ensure that they fully reflect the Federal Food, Drug, and Cosmetic Act.</td>
</tr>
<tr>
<td>Docket # 96N-0149</td>
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<tr>
<td>68 FR 22341</td>
<td>Apr. 28, 2003</td>
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<td>Docket # 95N-0309</td>
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<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>61 FR 60661 Docket # 96N-0364*</td>
<td>Nov. 29, 1996</td>
<td>Advance Notice of Proposed Rulemaking</td>
<td>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.</td>
</tr>
<tr>
<td>61 FR Part 67243 Docket # 96N-0421 and # 94P-0453</td>
<td>Dec. 20, 1996</td>
<td>Proposed Rule</td>
<td>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.</td>
</tr>
<tr>
<td>62 FR 67771 Dockets # 91N-384H and 96P-0500</td>
<td>Dec. 30, 1997</td>
<td>Advance Notice of Proposed Rulemaking; Extension of Comment Period</td>
<td>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.&quot; FDA needs additional time to conduct rulemaking on whether to amend the sodium content requirements for foods labeled “healthy.&quot;</td>
</tr>
<tr>
<td>63 FR 1078 Dockets # 96P-0023 and 96P-0179</td>
<td>Jan. 8, 1998</td>
<td>Proposed Rule; Extension of Comment Period</td>
<td>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.”</td>
</tr>
<tr>
<td>63 FR 20147 Docket # 94P-0043</td>
<td>Apr. 22, 1998</td>
<td>Proposed Rule</td>
<td>FDA proposed rule to amend the regulation for crabmeat by adding <em>Callinectes sapidus</em> to those listed in the regulation and assigning it the common name “blue crabmeat.”</td>
</tr>
<tr>
<td>65 FR 54686 Dockets # 00P-1275 and 00P-1276</td>
<td>Sept. 8, 2000</td>
<td>Interim Final Rule; Comment Period Reopened</td>
<td>FDA authorized the use of health claims asserting the relationship between plant sterol/stanol esters and reduced risk of coronary heart disease.</td>
</tr>
<tr>
<td>Docket #</td>
<td>Date</td>
<td>Type of Rulemaking</td>
<td>Description</td>
</tr>
<tr>
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</tr>
<tr>
<td>02N-0276</td>
<td>Feb. 3, 2003</td>
<td>Proposed Rule</td>
<td>FDA proposed rule to require all domestic and foreign facilities that process, pack or hold food to register with FDA by December 12, 2003.</td>
</tr>
<tr>
<td>00P-0685</td>
<td>Jul. 3, 2003</td>
<td>Advance Notice of Proposed Rulemaking</td>
<td>FDA requested comments on a petition to revoke standards for low-fat yogurt and nonfat yogurt and to amend standards for yogurt and cultured milk.</td>
</tr>
<tr>
<td>03N-0076</td>
<td>Jul. 11, 2003</td>
<td>Advance Notice of Proposed Rulemaking</td>
<td>FDA solicited information and data that can be used to establish new nutrient content claims about <em>trans</em> fat and required statements to enhance consumer understanding.</td>
</tr>
</tbody>
</table>
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.