

NPA Comment Tracker

Title	NPA Comment Date	FR Publication Date	Document Type	Organization	Status	Docket #	OMB Control Number	Promulgation Date	Important Dates
Agency Information Collection Activities; Proposed Collection; Comment Request; Foreign Supplier Verification Programs for Food Importers		October 22, 2018	Notice	FDA		FDA-2011-N-0143			Submit either electronic or written comments on this document by December 20, 2018.
United States-Mexico-Canada Agreement: Likely Impact on the U.S. Economy and on Specific Industry Sectors		October 16, 2018	Notice	USITC		TPA-105-003			<p><i>October 29, 2018:</i> Deadline for filing requests to appear at the public hearing</p> <p><i>October 30, 2018:</i> Deadline for filing prehearing briefs and statements</p> <p><i>November 15, 2018</i> and continuing on <i>November 16, 2018</i> if necessary: Public hearing</p> <p><i>November 23, 2018:</i> Deadline for filing posthearing briefs</p> <p><i>December 20, 2018:</i> Written submissions from the public Transmittal of Commission report to the President and Congress: No later than 105 days after the President enters into the agreement.</p>
Use of the Names of Dairy Foods in the Labeling of Plant-Based Products	September 28, 2018	September 28, 2018	Notice	FDA		FDA-2018-N-3522			Submit either electronic or written comments on this document by November 27, 2018.
Policy Regarding Quantitative Labeling of Dietary Supplements Containing Live Microbiols: Guidance for Industry	September 1, 2018	August 7, 2018	Notice	FDA		FDA-2011-D-0376			Submit either electronic or written comments on the draft guidance by November 6, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.
Request for Comments Concerning Proposed Modification of Action Pursuant to Section 301: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation	August 20, 2018	July 17, 2018	Notice	USTR	Dr. Fabricant testified before the USTR Section 301 Committee	USTR-2018-0026			
Request for Comments Concerning Proposed Modification of Action Pursuant to Section 301: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation	August 17, 2018	July 17, 2018	Notice	USTR	Written comments submitted to USTR	USTR-2018-0026			
Request for Comments Concerning Proposed Modification of Action Pursuant to Section 301: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation	July 27, 2018	July 17, 2018	Notice	USTR	Request to testify at public hearing & summary of proposed testimony submitted	USTR-2018-0026			
Agency Information Collection Activities; Proposed Collection; Comment Request; Petition To Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements	July 16, 2018	April 9, 2018	Notice	FDA		FDA-2018-N-1011	0910-0608		

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National Bioengineered Food Disclosure Standard	July 3, 2018	May 4, 2018	Proposed Rule	USDA		AMS-TM-17-0050	0581-NEW	60 days after the date of the final rule's publication in FR. Compliance date of January 1, 2020, with a delayed compliance date of January 1, 2021 for small food manufacturers. Compliance date for nutrition facts and supplement facts label final rule and the serving size final rule is January 1, 2020.	USDA intends that any final rule resulting from this rulemaking would become effective 60 days after the date of the final rule's publication in the Federal Register, with a compliance date of January 1, 2020, and with a delayed compliance date of January 1, 2021, for small food manufacturers. The proposed compliance date of January 1, 2020, is intended to align with FDA's proposed rule to extend the compliance dates for the changes to the Nutrition Facts and Supplement Facts label final rule and the Serving Size final rule from July 26, 2018, to January 1, 2020, for manufacturers with \$10 million or more in annual food sales.
Drug Products Labeled as Homeopathic; Draft Guidance for Food and Drug Administration Staff and Industry; Availability	March 20, 2018	December 20, 2017	Notice	FDA		FDA-2017-D-6580			
Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease; Extension of Comment Period	March 19, 2018	January 17, 2018	Proposed Rule	FDA		FDA-2017-N-0763			
Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration	February 5, 2018	September 8, 2017	Proposed Rule	FDA		FDA-2017-N-5093			
Review of Existing Center for Food Safety and Applied Nutrition Regulatory and Information Collection Requirements	February 5, 2018	September 8, 2017	Proposed Rule	FDA		FDA-2017-N-5094			
FDA Citizen Petition RE: 100 Percent Identity Testing Requirement for Dietary Ingredients	December 8, 2017		Rule	FDA		FDA-2013-N-1152		24-Aug-07	
Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration	December 7, 2017	September 8, 2017	Proposed Rule	FDA		FDA-2017-N-5093			
Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration	December 7, 2017	December 6, 2017	Proposed Rule			FDA-2017-N-5093			
Development of a List of Pre-Dietary Supplement Health and Education Act Dietary Ingredients; Public Meeting; Request for Comments	December 4, 2017	September 6, 2017	Notice	FDA		FDA-2017-N-4625			
Reducing Unnecessary Regulatory Burden	November 15, 2017	August 15, 2017	Proposed Rule	SBA	Comment submitted on November 15th, 2017	SBA-2017-0005			
Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Proposed Extension of Compliance Dates	November 1, 2017	May 4, 2018	Notice	FDA		FDA-2012-N-120 & FDA-2004-N-0258		Effective July 26, 2016. Compliance date is July 26, 2018 for manufacturers with \$10 million or more in annual food sales, and July 26, 2019 for manufacturers with less than \$10 million in annual food sales. On October 2, 2017, FDA published a proposed rule to extend the compliance dates to January 1, 2020 and January 1, 2021, respectively.	Effective July 26, 2016. Compliance date is July 26, 2018 for manufacturers with \$10 million or more in annual food sales, and July 26, 2019 for manufacturers with less than \$10 million in annual food sales. On October 2, 2017, FDA published a proposed rule to extend the compliance dates to January 1, 2020 and January 1, 2021, respectively.
FDA Citizen Petition to Stay and for Reconsideration (the Food Labeling Rule of July 26, 2016) from Porzio, Bromberg & Newman	June 16, 2017			FDA					
Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling: Draft Guidance for Industry	February 21, 2017		Notice	FDA		FDA-2016-D-2241	0910-NEW		

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Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition; Draft Guidance for Industry	February 13, 2017	January 13, 2017	Notice	FDA		FDA-2011-D-3401	0910-0813		The announcement of the guidance is published in the Federal Register on March 2, 2018.
Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry	December 12, 2016		Notice	FDA		FDA-2011-D-0376	0901-0606		
Withdrawal of Notice of Intent to Temporarily Place Mitragynine and 7-Hydroxymitragynine Into Schedule I	November 29, 2016	October 13, 2016	Proposed Rule	DEA		DEA-442W			
Request for Comment on the Status of Vinpocetine	November 7, 2016	September 7, 2016	Notice	FDA	Comments explaining how Vinpocetine fits under 201 (ff), NPA support of lawful use, submitted.	FDA-2016-N-2523			
Request for Comment on the Status of Vinpocetine: Request for Extension of Comments	October 3, 2016		Notice	FDA		FDA-2016-N-2523			
Notice of Opportunity for Public Comment on the Office of Dietary Supplements Draft 2016-2021 Strategic Plan	September 30, 2016	September 15, 2016	Notice	NIH		2016-22233			
REQUEST FOR EXTENSION OF COMMENT PERIOD. "Substances Generally Recognized as Safe"	August 29, 2016	August 17, 2016	Rule	FDA		FDA-1997-N-0020	0910-0342	17-Oct-16	
REQUEST FOR EXTENSION OF COMMENT PERIOD. "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry."	August 24, 2016	August 12, 2016	Notice	FDA		FDA-2011-D-0376	The collections of information in 21 CFR part 111 have been approved under OMB control number 0901-0606, and the collections of information in § 190.6 have been approved under OMB control number 0910-0330.		
WIC: Agency Information Collection Activities; Proposals, Submissions, and Approvals	June 6, 2016	March 10, 2016		ERS		2016-07850	0584-0580		
Guidance for Industry: Frequently Asked Questions About Medical Foods; Second Edition	May 23, 2016	May 13, 2016	Notice	FDA		<u>FDA-2013-D-0880</u>	The collection of information under 21 CFR 1, part 1 subpart H has been approved under OMB control number 0910-0502. The collections of information in 21 CFR 113.100 and 114.100 (a) through (d) have been approved under OMB control number 0910-0037.		
Food Labeling; Notification Procedures for Statements on Dietary Supplements	May 10, 2016	March 11, 2016	Notice	FDA		FDA-2009-N-0221	0910-0331		
Use of the Term "Natural" in the labeling of Human Food Products; Request for Information and Comments	May 10, 2016	November 12, 2015	Proposed Rule	FDA		<u>FDA-2014-N-1207</u>			
Notice of Public Meeting for the National Organic Science Board	April 25, 2016	March 16, 2016		NOSB	Dr. Fabricant provided oral comments to NOSB	AMS-NOP-15-0085-0001			
Notice of Public Meeting for the National Organic Science Board	April 20, 2016			USDA		USDA-AMS-NOP			

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Notice of Public Meeting for the National Organic Science Board	April 14, 2016	March 16, 2016		NOSB	Written comments submitted to USDA and NOSB	AMS-NOP-15-0085-0001			
Department of Agriculture, Agriculture Marketing Services; Notice of Public Meeting for the National Organic Science Board	April 7, 2016	March 16, 2016	Notice	NOSB		AMS-NOP-15-0085-0001, NOP-15-16			
Over-the-Counter Sunscreens: Safety and Effectiveness Data; Draft Guidance for Industry; Availability	February 22, 2016	November 23, 2015	Notice	FDA		FDA-2015-D-4021			
OEHHAs Proposed Repeal of Article 6 and Adoption of New Article 6- Clear and Reasonable Warnings	January 25, 2016			CA		http://oehha.ca.gov/proposition-65/cnr/proposed-rulemaking-and-announcement-public-hearing-title-27-california-code			
Sunscreen Innovation Act: Nonprescription Sunscreen Drug Products- Content and Format of Data Products-content and Format of Data Submissions; Draft Guidance for Industry; Availability	January 22, 2016	November 23, 2015	Notice	FDA		FDA-2015-D-4033			Submit either electronic or written comments on Agency guidances at any time.
Sunscreen Innovation Act: Section 586(c) Advisory Committee Process; Draft Guidance for Industry; Availability	January 22, 2016	November 23, 2015	Notice	FDA		FDA-2015-D-3990			Submit either electronic or written comments on Agency guidances at any time.
Nonprescription Sunscreen Drug Products-Content and Format of Data Submissions to Support a GRASE Determination Under the Sunscreen Innovation Act	January 22, 2016	November 23, 2015	Notice	FDA		FDA-2015-D-4033			Submit either electronic or written comments on Agency guidances at any time.
Notice of Opportunity for Public Comment on the Dietary Supplement Label Database	December 31, 2015	October 29, 2015	Notice	NIH		2015-29177			
Management Standards for Hazardous Waste Pharmaceuticals	December 24, 2015	September 25, 2015		EPA		EPA-HQ-RCRA-2007-0932			
Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants; Guidance for Industry; Availability	December 24, 2015	November 24, 2015	Notice	FDA		FDA-2000-D-0075			
EPA's Proposed management Standards for Hazardous Waste Pharmaceuticals	December 24, 2015	November 5, 2015	Proposed Rule	EPA		HQ-RCRA-2007-0932			
Extension of Comment Period: Notification of Request for Comments: Use of the Term "Natural" in the Labeling of Human Food Products. 80 Federal Register 69905-69909. (November 12, 2015)	November 30, 2015	November 12, 2015	Proposed Rule	FDA		FDA-2014-N-1207.			
OEHHA Pre-Regulatory Draft Proposal to mandate use of the arithmetic mean for calculating exposure to chemicals by the "average" user	November 17, 2015			CA					
OEHHA Pre-Regulatory Draft Proposal to provide guidance on how to calculate the contribution of chemicals (lead and arsenic) from a naturally occurring source	November 12, 2015			CA					
OEHHA Pre-Regulatory Draft Proposal to repeal/amend the safe harbor level for lead (Pb)	October 28, 2015			CA					
Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards	October 15, 2015	July 24, 2015	Rule	FDA		FDA-2011-N-0146	0910-0750	13-Jan-17	This rule is effective January 13, 2017.
Food Labeling: Revision of the Nutrition and Supplement Label Facts	October 13, 2015	September 10, 2015	Proposed Rule	FDA		FDA-2012-N-1210			
Draft Regulation (OEHHA's new Article 6: "Clear and Reasonable Warnings")	October 1, 2015			CA					

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Toxicological Principles for the Safety Assessment of Food Ingredients; Public Meeting on Updates and Safety and Risk Assessment Considerations	October 1, 2015	February 2, 2015	Notice	FDA		FDA-2014-N-1497			
Evaluating the Food and Drug Administration's Regulatory Framework for Homeopathics After a Quarter-Century	August 21, 2015	June 10, 2015	Proposed Rule	FDA		FDA-2015-N-0540			
Notice of Intent to List Chemicals by the Labor Code Mechanism: Aloe Vera, Whole Leaf Extract and Goldenseal Root Powder	June 9, 2015			CA					
Toxicological Principles for the Safety Assessment of Food Ingredients; Public Meeting on Updates and Safety and Risk Assessment Considerations	May 11, 2015	February 2, 2015	Notice	FDA		FDA-2014-N-1497			
OEHHA Pre-Regulatory Draft ("Proposed Amendments to Article 6 Clear and Reasonable Warnings")	April 8, 2015			CA					
Agency Collection Activities; Premarket Notification for a New Dietary Ingredient	March 27, 2015	March 18, 2014	Notice	FDA		FDA-2013-N-0878	0910-0330		
DNA Barcoding	March 17, 2015			White Paper					
Agency Collection Activities; Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act	March 13, 2015	February 11, 2015	Notice	FDA		FDA- 2011-N-0403	0910-0626		
Agency Collection Activities; Petition to Request an Exemption from 100 Percent Identity Testing of Dietary Ingredients	December 29, 2014	November 28, 2014	Notice	FDA		FDA-2013-N-1152			
National Food Safety Standard – General Standard for Sports Nutrition Food")	December 19, 2014			INTL					
Administrative Regulations for Nutritional Information Requirements for Nutritional Supplements	November 29, 2014			INTL					
OEHHA Potential Regulations Workshop ("Comments the Naturally Occurring Regulation (25501)")	November 17, 2014			CA					
Food Labeling: Revision of the Nutrition and Supplement Facts Labels	August 1, 2014	May 27, 2014	Proposed Rule	FDA		FDA-2012-N-1210			
Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion	August 1, 2014			FDA		FDA-2014-N-0258			
Draft – China Food Safety Law Amendment	July 31, 2014			INTL					
Proposed Amendments to Article 6 Clear and Reasonable Warnings")	June 13, 2014			CA					
CGMP in manufacturing packaging, labeling, or holding operations for dietary supplements	February 18, 2014	Decmeber 19, 2013	Notice	FDA		FDA-2013-N-1619	0910-0606		
Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion	January 1, 2014			FDA		FDA-2004-N-0258			
FDA Letter to FDA Commissioner Hamburg to remove dietary supplements and ingredients from the Redbook public meeting	January 1, 2014			FDA					
Letter to FDA Medwatch Alert (Attn: Steve Immergut) ("Risk of Invasive Fungal Disease in Immunocompromised Persons Given Dietary Supplements Formulated to Contain Live Bacteria or Yeast")	January 1, 2014			FDA					
Premarket Notification for NDI	October 25, 2013			FDA		FDA-2013-N-0878			
GMO	March 18, 2013			White Paper					
Safer Consumer Product Proposed Regulations: CA regulatory notice register	October 11, 2012			CA		Z-2012-0717-04			
Safer consumer Products Informal Draft Regulations	December 30, 2011			CA		R-2011-02			
Draft Guidance for Industry: Dietary Supplements NDI Notifications	November 30, 2011	August 19, 2011		FDA		FDA-2011-N-0376	0910-0330		
FSMA Domestic and Foreign Facility Reinspections	November 30, 2011	August 1, 2011	Notice	FDA		FDA-2011-N-0528			

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Burden of FDA FSMA Fee Amounts on Small Business	November 30, 2011	August 1, 2011	Notice	FDA		FDA-2011-N-0529			
Interim Final Rule; Criteria Used to Order Administrative detention of food for human or animal consumption	July 29, 2011	May 5, 2011	Rule	FDA		FDA-2011-N-0197		3-Jul-11	Effective date: This interim final rule is effective July 3, 2011.
Proposed Regulation for Green Chemistry Hazard Traits	February 15, 2011			CA					
Draft Guidance for Industry on Investigational New Drug Applications- Determining whether human research studies can be conducted w/o an Investigational new drug application	January 12, 2011	October 14, 2010	Notice	FDA		FDA-2010-D-0503	0910-0014		
Proposed, Revised Green Guides, 16 CFR Part 260, Project No. P954501; Request for comment	December 10, 2010			FTC		2010-25000			
Comments to the Office of Environmental Health Hazard Assessment, California Environmental Protection Agency on the Green Chemistry Pre-Regulatory Draft	September 13, 2010			CA					