CFSAN/Office of Food Additive Safety July 2007

Summary of All GRAS Notices

The summary tables that are immediately below provide the following information about GRAS notices received within each year since 1998, when FDA r

- The name of the substance
- The file number (GRN No.) that FDA has assigned to the notice
- A hyperlink to the letter that FDA sent in response to the notice

Within the summary table for each year, the first row provides a hyperlink to a table that provides more details about the GRAS notices received in that year the notice corresponding to the proposed "GRAS exemption claim" (proposed 21 CFR 170.36(c)(1)), including the following information, which we propose the public:

- The name of the notifier and a hyperlink to the notifier's address
- The intended conditions of use
- · The basis for the GRAS determination

Persons interested in obtaining additional data and information in the notice may obtain a copy of those data and information that are disclosable by request Freedom of Information Act (see FDA's document entitled "How to Request Information or Make a Freedom of Information Request").

These tables are current as of June 29, 2007, and therefore, do not show any new notices filed by FDA, or response letters issued by FDA, after that date. T approximately monthly.

For further information about the GRAS notification program, telephone Dr. Paulette Gaynor at (301) 436-1192 or send a question by electronic mail to pre

List of the substances that are the subject of each GRAS Notice and the file number that FDA has assigned to the notice (GRN No.).

GRAS Notices Received in 2007

	<u>Details about Notices Received in 2</u> (GRN No. 219-227)	<u>007</u>
GRN No.	Substance	FDA's L
227	Olestra	Pendin
226	Krill-derived lecithin	Pendin
225	Catechins from green tea extract	Pendin





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ARSCK IIISCUIIIA	182 captures 4 Apr 2001 - 23 Oct 2011	200	05 6 2007	2008
221	Lutein			Penair
220	alpha-Glycosyl isoquercitrin			Pendir
219	Ammonium phosphatide		FE	A has no c

GRAS Notices Received in 2006

Details about Notices Received in 2006

GRN No. 189-218)		
GRN No.	Substance	FDA's L
218	Bacteriophage P100 preparation from Listeria innocua	FDA has no q
217	Tailored tryglycerides containing approximately 12 percent medium-chain fatty acids	Pendir
216	Lipase enzyme preparation from Rhizopus oryzae	FDA has no q
215	Actinidia arguta extract	Pendin
214	Asparaginase enzyme preparation from <i>Aspergillus niger</i> expressing the asparaginase gene from <i>A. niger</i>	FDA has no c
213	Hydroxypropyl methylcellulose - expanded substitution pattern (HPMC-ESP)	FDA has no c
212	Phospholipase A2 enzyme preparation from <i>Streptomyces violaceruber</i> expressing a gene encoding phospholipase A2 from the same species	FDA has no c
211	Xanthan gum (reduced pyruvate)	FDA has no q
210	Water soluble tomato concentrate	FDA has no c
209	L-theanine	FDA has no c
208	Erythritol	FDA has no c
207	Barley fiber	FDA has no c
206	Phytosterol esters and diglycerides resulting from transesterification of vegetable oils/fats with soy phytosterols	FDA has no c
205	Pullulanase enzyme preparation from <i>Bacillus subtilis</i> expressing the pullulanase gene from <i>B. acidopullulyticus</i>	FDA has no q
204	Phospholipase C enzyme preparation from <i>Pichia pastoris</i> expressing a heterologous phospholipase C gene	FDA has no c
203	Erythritol fatty acid esters	At notifier's request, FDA cease
202	Polyoxyethanyl-alpha-tocopheryl sebacate (PTS)	FDA has no c
201	Asparaginase enzyme preparation from <i>Aspergillus oryzae</i> expressing the asparaginase gene from <i>A. oryzae</i>	FDA has no c
200	Tailored triglycerides enriched in omega-3 fatty acids from fish oil	FDA has no c
199	Concentrated hydrolyzed milk protein	FDA has no c
100	Data in Land Blood Burnership from Lindows in the	EDA 1



	·	
194	Carbon monoxide	Pendin
193	Fish oil (predominantly sardine and anchovy); tuna oil	FDA has no q
192	High 2-palmitic vegetable oil	FDA has no q
191	Lysozyme (human) purified from rice	Pendin
190	Hydroxypropyl methylcellulose	At notifier's request, FDA ceas Resubmitted as G
189	Lactoferrin (human) purified from bovine milk	Pendin

GRAS Notices Received in 2005

At notifier's request, FDA ceas

Additional correspondence

FDA has no c

Details about Notices Received in 2005 (GRN No. 163-188) GRN No. **Substance** FDA's L 188 Carbon monoxide Pendir 187 L(+) Tartaric acid (alternative method of manufacture) FDA has no c 186 Soy lecithin enzymatically modified to have increased phosphatidylserine FDA has no c 185 Concentrated tomato lycopene extract FDA has no c 184 Isomaltulose FDA has no c Phospholipase A2 enzyme preparation from Aspergillus niger expressing a gene encoding a 183 FDA has no c porcine phospholipase A2 182 Hydrolyzed wheat gluten isolate; pea protein isolate FDA has no c 181 Phytosterols FDA has no c 180 Allyl isothiocyanate FDA has no c FDA has no c 179 Polyglycerol polyricinoleic acid 178 Sodium iron EDTA FDA has no c 177 Plant sterol esters FDA has no c 176 Plant sterols and plant sterol esters from vegetable oils or sterols/stanols from tall oil FDA has no c 175 Saccharomyces cerevisiae strain ECMo01 with enhanced expression of urea amidolyase FDA has no c 174 Lysozyme (human) enzyme preparation from rice At notifier's request, FDA ceas FDA has no q 173 Lycopene from Blakeslea trispora some uses may require a



172

171

Isomalto-oligosaccharide

Lactobacillus acidophilus, Lactobacillus lactis, and Pediococcus acidilactici



http://www.cfsan.fda.gov:80/~rdb/opa-gras.html

182 captures

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FDA has no c

		2006 2007 2008		
	100	Carbon monoxide	At nouner's request, FDA ceas	
	165	Quillaia extract type 1	FDA has no	
	164	Lauramide arginine ethyl ester	FDA has no c	
		Laurannue arginine euryr ester	Additional correspondence	
	163	omata nula navydar	FDA has no c	
		Tomato pulp powder	Additional correspondence	

GRAS Notices Received in 2004

Details about Notices Received in 2004 (GRN No. 143-162)

(GRN No. 143-162)			
GRN No.	Substance	FDA's L	
162	Lactoferrin (human) purified from rice	At notifier's request, FDA cease	
161	Chlorine dioxide, generated using sodium chlorite in calcined or sulfated kaolin clay	FDA has no c	
160	Micro-algal oil (Ulkenia sp.)	At notifier's request, FDA cea	
159	Carnobacterium maltaromaticum strain CB1	FDA has no o	
158	Lipase preparation from Aspergillus niger expressing a gene encoding a lipase from Candida antartica	FDA has no o	
157	Calcium propionate (alternative method of manufacture)	FDA has no c	
156	Tomato lycopene extract 6 percent, tomato lycopene extract 1.5 percent, and crystallized tomato lycopene extract	FDA has no q some uses may require a	
155	alpha-Cyclodextrin	FDA has no c	
154	Dried orange pulp	FDA has no c	
153	Conjugated linoleic acid	At notifier's request, FDA cease	
152	Sodium iron EDTA	FDA has no c	
151	Ethanol (ethyl alcohol)	FDA has no o	
150	Glucosamine hydrochloride prepared from chitin obtained from Aspergillus niger	At notifier's request, FDA cease	
149	Beta-glucanase enzyme preparation from Trichoderma harzianum	FDA has no o	
148	Vegetable oil conjugated linoleic acid preparation	At notifier's request, FDA cea	
147	Fish protein	FDA has no o	
146	Salmon oil	FDA has no o	
145	Phospholipase A2 enzyme preparation from Streptomyces violaceoruber	FDA has no o	
144	Adenosine 5'-monophosphoric acid and its monosodium and disodium salts	FDA has no o	



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Carbon monoxide

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	4 Apr 2001 - 23 Oct 2011	2000 2007 2000
GKITTO.	Substance	IDASL
142	Phospholipase enzyme preparation from <i>Aspergillus oryzae</i> expressing the gene encoding a phospholipase A1 from <i>Fusarium venenatum</i>	FDA has no o
141	Polyvinyl alcohol	FDA has no o
140	Crystalline lutein	FDA has no c some uses may require a
139	Cassia gum	At notifier's request, FDA cea
138	Fish oil	FDA has no c
137	Algal oil (Schizochytrium sp.)	FDA has no o
136	Calcium gluconate	FDA has no c
135	ε-Polylysine	FDA has no c
134	Soy protein hydrolyzate with enzyme-modified lecithin	FDA has no c
133	Volatile oil of mustard	FDA has no o
132	Lactase enzyme preparation from Aspergillus niger	FDA has no o
131	High 2-palmitic vegetable oil	FDA has no o
		Additional corre
130	Bovine milk-derived lactoferrin	FDA has no c
129	Sucrose fatty acid esters	FDA has no c
128	Skim milk or dextrose cultured with Propionibacterium freudenreichii subsp. shermanii	FDA has no c
127	Spirulina, the dried biomass of Arthrospira platensis	FDA has no o some uses may require a
126	Alpha-amylase enzyme preparation from <i>Pseudomonas fluorescens</i> Biovar I expressing a gene encoding a hybrid alpha-amylase derived from three microorganisms within the order <i>Thermococcales</i>	FDA has no o
125	Grape seed extract and grape pomace extract	FDA has no q some uses may require a
124	Grape seed extract	FDA has no o
123	Laminaria japonica broth and extract powder	FDA has no
122	Laccase enzyme preparation produced by <i>Aspergillus oryzae</i> expressing the gene encoding a laccase from <i>Myceliophthora thermophila</i>	FDA has no
121	Xanthan gum	FDA has no
120	Saccharomyces cerevisiae strain ML01 carrying a gene encoding the malolactic enzyme from Oenococcus oeni and a gene encoding malate permease from Schizosaccharomyces pombe	FDA has no o



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