WILD
WE CREATE Great Taste

19 May 2006

RECEIVED
USDA NATIONAL
ORGANIC PROGRAM
2006 MAY 25 P 12:03

Program Manager
USDA/AMS/TMP/NOP
1400 Independence Avenue SW
Room 4008-So., Ag Stop 0268
Washington, DC 20250

Dear Sir/Madam,

To assure that certain colors from natural sources remain on the NOP National List of non-organically produced ingredients we offer you the attached petitions for six different color categories.

Colors from Fruit Juices as set forth in 21 CFR 73.250
Colors from Vegetable Juices as set forth by 21 CFR 73.260
Beta-Carotene from natural sources as set forth by 21 CFR 73.95
Colors from Annatto as set forth by 21 CFR 73.30
Colors from Turmeric as set forth by 21 CFR 73.600
Colors from Paprika as set forth by 21 CFR 73.340

We understand that these petitions for colors are now absolutely essential for the NOSB to approve them so colors remain on the National List after Sunset on October 21, 2007. We have used the petition application form that is available on the NOP website. We have also included applicable flow charts for each of these six color categories. We look forward to working with you to assure that these colors from natural sources remain on the NOP National List well beyond October of 2007. If you have any questions or if you require any additional information, please do not hesitate to contact us.

Yours truly,

John T. Martin
Director, Scientific & Regulatory Affairs
WILD Flavors, Inc.
P: 859-342-3798
F: 859-342-3738
Email: jtmartin@wildlflavors

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance : Annatto Extract 21 CFR 73.30

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			21 CFR 73.30
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? Substance Annatto Extract 21 CFR 73.30

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]			X	
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X			
4. Is there a natural source of the substance? [§205.600 b.1]	X			annatto seed, *Bixa orellana* L., are of natural origin
5. Is there an organic substitute? [§205.600 b.1]		X		
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			X	
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
9. Is there any alternative substances? [§6518 m.6]		X		
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b)are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices?

Substance Annatto Extract 21 CFR 73.30

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			X	
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]		X		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]	X			
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;		X		
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Item A – This petition involves the continued inclusion of exempt colors from annatto described in 21 CFR 73.30 as a non-agricultural (non-organic) substance allowed in or on processed products labeled as "organic" or "made with organic".

Item B

1,) Annatto Extract
2.) WILD Flavors, Inc. 1261 Pacific Avenue Erlanger, KY 41018 859-342-3600
3.) To add color to food/beverages using exempt colorants from natural sources of annatto seeds
4.) Not intended for use on crops or livestock. Adding color is the mode of action.
5.) See attached flow chart
6.) Not applicable – WILD Flavors is not currently a certified manufacturer/handler
7.) Refer to 21 CFR 73.30
8.) 8015-67-6
9.) Refer to evaluation criteria
10.) Not applicable – MSDS available upon request.
11.) All categories of annatto colors are approved for use in accordance with 21 CFR 73.30 and are GRAS.
12.) Non-synthetic colors should remain on the National List as described in 7 CFR 205.605

NOSB RECOMMENDED DECISION

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: _____ | Substance: _____

A. Evaluation Criteria (Documentation attached; committee recommendation attached)

		Criteria Satisfied?		
1.	Impact on humans and environment	Yes	No	(see B below)
2.	Availability criteria	Yes	No	(see B below)
3.	Compatibility & consistency	Yes	No	(see B below)

B. Substance fails criteria?

Criteria category: _____

Comments:

C. Proposed Annotation: _____

_____

Basis for annotation:

To meet criteria above: ____ Criteria: _____

Other regulatory criteria: ____ Citation: _____

D. Final Board Action & Vote: Motion by: _____ Second: _____

Vote:

Yes: _____

No: _____

Abstain: _____

Agricultural		Nonagricultural		Crops	
Synthetic		Not synthetic		Livestock	
Allowed[1]		Prohibited[2]		Handling	
No restriction		Deferred4		Rejected[3]	

1—substance voted to be added as "allowed" on National List

Annotation: _____

_____

2—substance to be added to "prohibited" paragraph of National List

Describe why a prohibited substance: _____

_____

3—substance was rejected by vote for amending National List

Describe why material was rejected: _____

_____

4-substance was recommended to be deferred

Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up. _____

_____

E. Approved by NOSB Chair to transmit to NOP:

_____ _____

Dave Carter, NOSB Chair Date

F. NOP Action: Include in FR to amend National List:

Return to NOSB Reason: _____

_____ _____

Richard H. Mathews, Program Manager Date

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: _____ | Substance: _____

Committee: Crops Livestock Handling

A. Evaluation Criteria (Documentation attached; committee recommendation attached)

		Criteria Satisfied?		
4.	Impact on humans and environment	Yes	No	(see B below)
5.	Availability criteria	Yes	No	(see B below)
6.	Compatibility & consistency	Yes	No	(see B below)

B. Substance fails criteria?

Criteria category: _____

Comments:

C. Proposed Annotation: _____

_____

Basis for annotation:

To meet criteria above: ____ Criteria: _____

Other regulatory criteria: ____ Citation:_____

D. Recommended Committee Action & Vote: Motion by: _____

Seconded:_____

Vote:

Yes: _____

No: _____

Abstain: _____

Agricultural		Nonagricultural		Crops	
Synthetic		Not synthetic		Livestock	
Allowed[1]		Prohibited[2]		Handling	
No restriction		Deferred4		Rejected[3]	

1—substance voted to be added as "allowed" on National List

Annotation: _____

_____

2—substance to be added to "prohibited" paragraph of National List

Describe why a prohibited substance:_____

_____

3—substance was rejected by vote for amending National List

Describe why material was rejected:_____

_____

4-substance was recommended to be deferred

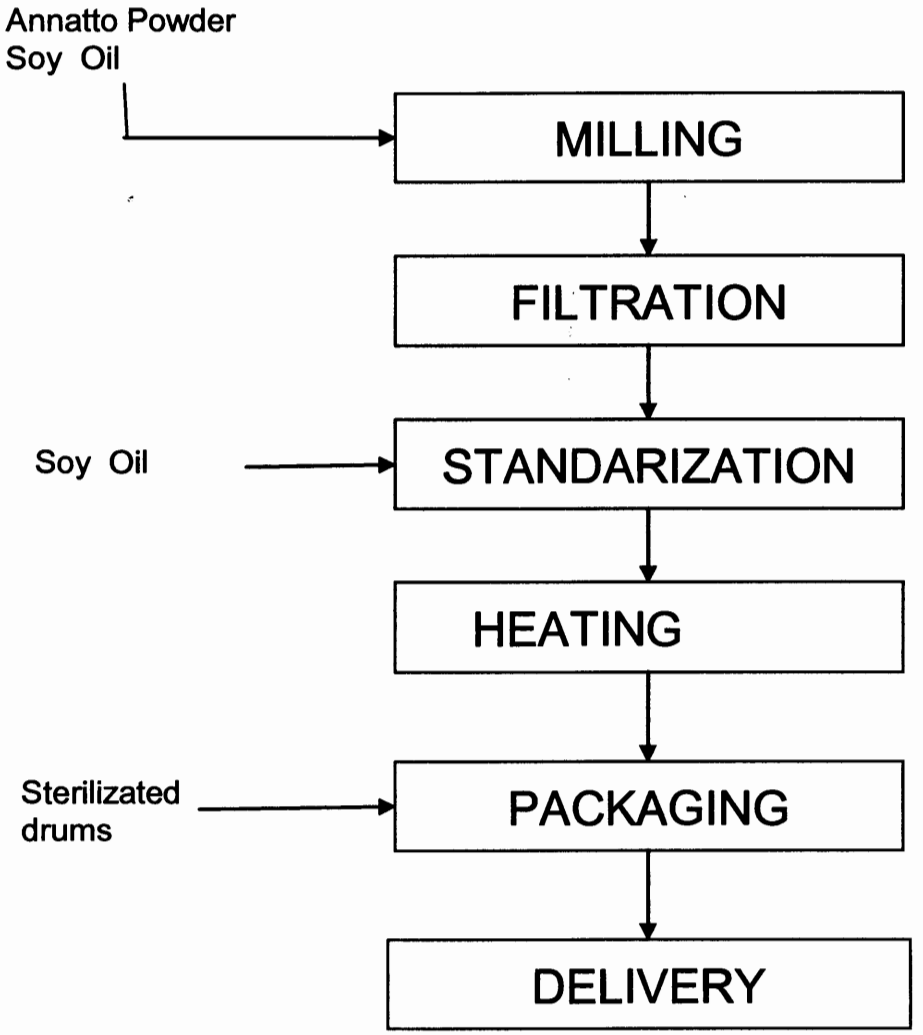
Describe why deferred; if follow-up is needed. If follow-up needed, who will follow up_____

_____

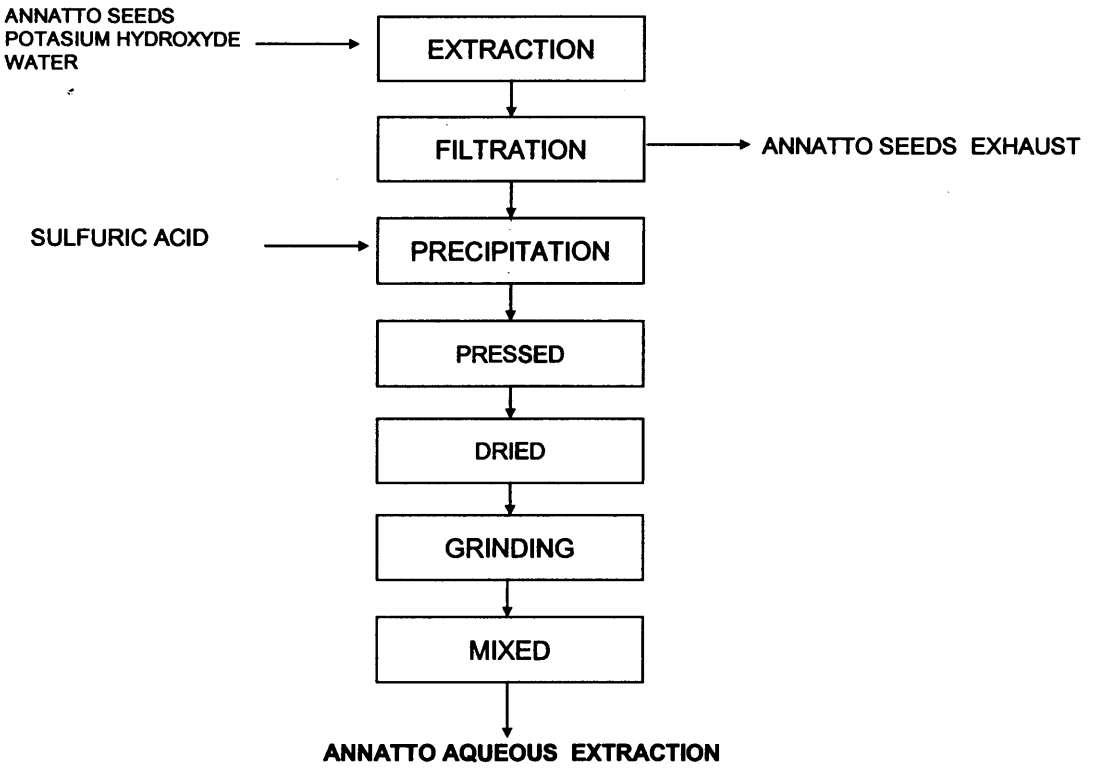
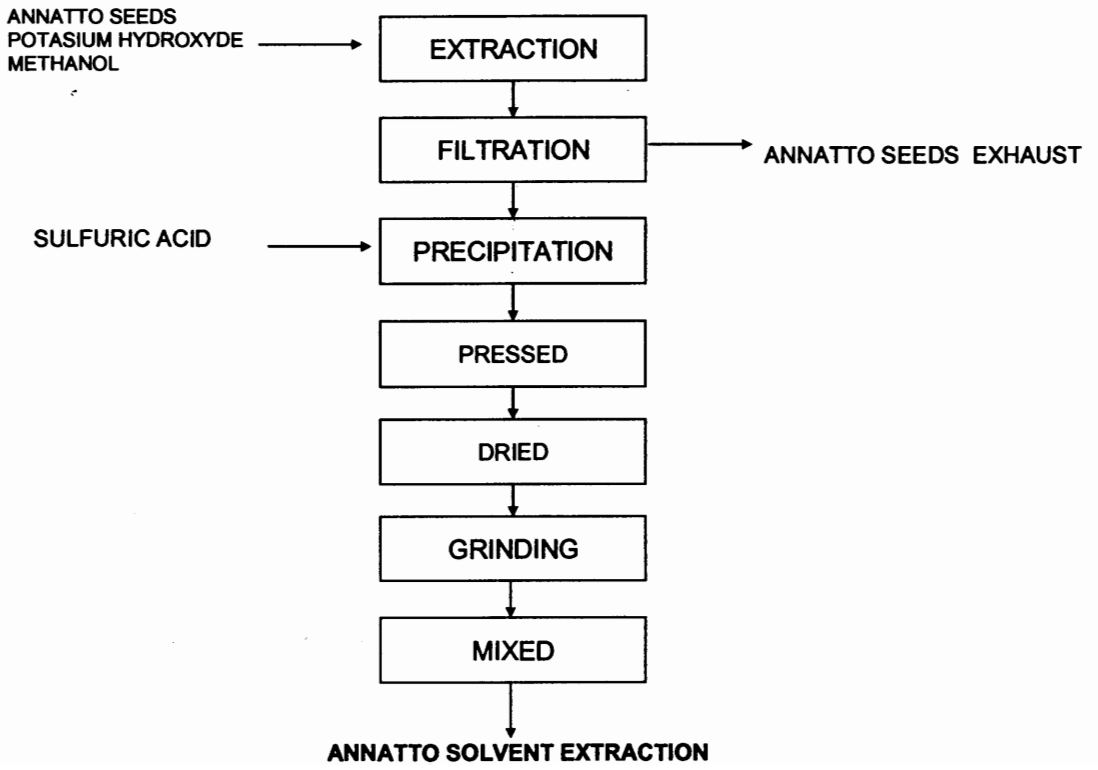
E. Approved by Committee Chair to transmit to NOSB:

Committee Chair _____ Date _____

ANNATTO OIL D-8



FLOW CHART- ANNATTO AQUEOUS EXTRACTION



FLOW CHART- ANNATTO SOLVENT EXTRACTION