







STEP BY STEP INSTRUCTIONS FOR FILLING OUT FEDERAL AND STATE SPECIAL CLAIMS APPLICATIONS

This sheet is intended for independent, niche meat producers who want to market their meat products using special claims such as "pasture-raised" or "grassfed" and want an easy-to-follow, step by step approach to completing the state and/or federal application. This sheet is meant to complement the Federal Form 7234-1 and/or the State Form MPIS Form 11 by providing examples and further instructions when applying for special claims on your products.







The plant inspection status will determine if the approval application is submitted to the state or federal labeling division. Fill out <u>FSIS FORM 7234-1</u> if your processor operates under USDA or TA inspection. Before filling out the application form, check with your processor to find out if they prefer to submit the label claim application to the federal labeling division or if they want you as the farmer to submit the application – both are acceptable. At NCDA inspected facilities, the processor will submit <u>MPIS FORM-11</u> to their Inspector In Charge (IIC). In both situations, you will want to work with your processor to complete parts of the application. Processors reserve the right to charge for additional time.

For more information about special claims and the approval process, please visit the Extension publication **Special Labeling Claims and the Approval Process for Niche Meat Production**. LF-003. Raleigh, NC: The Center for Environmental Farming Systems. Please refer to that publication to learn more about what qualifies as a special claim and general procedural and paperwork requirements when submitting the state or federal special claims application.

For regulatory questions, contact FSIS labeling division or NCDA Meat and Poultry Inspection included in the form instructions below.

INSTRUCTIONS FOR PREPARATION OF FSIS FORM 7234-1

Please refer to **FSIS FORM 7234-1** as you read the following detailed information on how to complete this application.

	coording to the Pagegregate Reduction Act of 1995, an agency may not conduct or sporsor, and a person is not respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number is not maintaining the data more needed, and ompleted this information collection is estimated to a vierage 7.5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and ompleted instructions are required to complete this information collection in estimated to a vierage 7.5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and ompleteling and reviewing the collection of information. This form had been approved by OMB for web distribution. PAGE						
_	U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE APPLICATION FOR APPROVAL OF LABELS, MARKING OR DEVICE FSIS has determined that information provided in items 11, 15, and 16 is exempt from mandatory disclosure under the Freedom of Information Act 5 U.S.C. 552(b)(4). APPLICANT: See Page 5 for instructions. 5a. NAME OF PRODUCT	AGENT NAME, ADDRESS, TELEPHONE NO. (If using an Agent, complete this block, otherwise leave blank.)	2. FOR USDA USE ONLY	3. FOR USDA USE ONLY	4. ESTABLISHMENT NO. / FOREIGN COUNTRY (If applicable) 4a. TYPE OF PRODUCT Egg Meat Poultry Other		
)	5b. HACCP PRODUCT 5b. HACCP PROCESS CATEGORY (Select of 0.3J.: Slaughter - all species 0.3B: Raw Product - ground 0.3C: Raw Product - not ground	SKETCH EXTENSION	PROVAL REQUESTED 7 TEMPORARY 7	7a. AREA OF PRINCIPAL DISP	LAY PANEL (Square Inches)		
,	03D: Thermally processed - commercially 03E: Not heat treated - shelf stable 03F: Heat treated - shelf stable 03G: Fully cooked - not shelf stable 03H: Heat treated but not fully cooked - not 03I: Product with secondary inhibitors - not	YES → DO NO	BEL PREVIOUSLY APPROVED? ate of approval: rior approval number: umber of labels on hand: umber of days requested:	7b. TOTAL AVAILABLE LABELING SPACE FOR ENTIRE PACKAGE (Square inches):			
3	Does this label include a "USDA-AMS Child I	Nutrition Program CN-Logo? Yes	□ No 9	9. (FOR USDA-AMS USE ONLY	') CN Identification Number Assigned		
0	Are there any special claims, guarantees, of Allergen Statements Animal Production/Breed/Raising Certified/Verified Environmental/Green Export Only Labels w/deviations from Dom Foreign Language Geographic/Undefined Style	Grading Ten	anic alth	cify			
1	NAME AND ADDRESS OF FIRM (B	Below and between dots)	12. SIGNATURE OF APPLICAN	T OR AGENT 13	13. DATE		
FS	SIS FORM 7234-1 (11/16/2011)	●	14. (FOR USDA USE ONLY) CO	ONDITIONS APPLYING TO USE OF	F LABELS OR DEVICE		

NOTES ABOUT COMPLETING THIS FORM

A. Preparation of Application

Submit two copies for each label application.

Application must be typed or it will be returned without evaluation.

B. Type of approval requested

Sketch: Self-explanatory. (See 9 CFR 317.4 & 381.132) Temporary and Extension of Temporary. Actual label or color litho take off to be used.

C. Foreign Language

Labels printed in foreign languages must be accompanied by English language translation.

D. Assembly of Application

Application Form, Product Formula, Processing Procedures, Continuation Sheet if applicable, Label, and any Supporting Documentation Staple with one or as few staples as possible. (Do not use paper clips). Supporting documentation is added to FSIS Form 7234-1 using extra pages not included in the form. Be sure when numbering application pages to include the supporting documentation in the total number of pages. This will ensure the reviewer sees the complete application.

E. Mail Completed Application to:

USDA, FSIS, OPPD, LPDD Labeling Distribution Unit Stop Code 3786, Patriots Plaza III, 8-168 1400 Independence Avenue, SW Washington, DC 20250-3700

HELPFUL HINT! At the top right of each page, fill in the total page numbers of the application, including any attachment pages. FSIS receives numerous special claim applications and numbering pages helps them to keep track of yours. Also, this application needs to be submitted typed.

The following instructions relate to numbered items on FSIS form 7234-1.

- 1. If using an Agent, provide the company name, address, and telephone number, otherwise leave blank. The agent is the main point of contact and can either be the producer/business or the processor. Some processors want the producer to be the point of contact, while other processors prefer to be the point of contact because they are responsible for adhering the label. This is a matter to discuss with your processor.
- 2 & 3. Leave blank, for USDA use only.
- 4. Establishment No./Foreign Country (if applicable) Self Explanatory.

 This is the processing plant's number where the product is packaged. If you don't know your processors' plant number you can, (1) Find the plant number on their USDA inspection seal [see example], (2) search for the plant under NCDA Meat and Poultry Inspection Division TA plant listing or USDA plant listing, or (3) ask your processor directly.



- 4a. Type of Product. Select one product type: Egg, Meat, Poultry, or Other (i.e. Exotic Species, Non-Amenable, Voluntary, etc.)
- 5a. Name of Product. Use common or descriptive product name, i.e., "Frankfurter, Cereal Added" or "Meat Patties in Gravy." (Do not use trade brand names or coined names, such as "Joe's Corn Dogs" or "Joe's Sloppy Joes.") If coined names such as "Corn Dogs" are used, also show true product name, such as "Batter Wrapped Wiener."

Put the name of the product here, such as "Hot Dogs", that will receive the special claim. If applying to make a special claim that applies to more than one single ingredient product, such as adding the pasture-raised claim to all fresh meat or poultry products, the applicant may ask for a "Blanket Approval." The blanket approval

allows applicant to submit one application for a special claim that applies to all single ingredient products. For example, in Box 5a write "Fresh Pork cuts – blanket approval." Itemized cuts should be listed in the processing procedures section of the application (Block 16).

**Please note: You can also add a special claim such as "pasture-raised" to a whole line of multi-ingredient products as long as the ingredients in those products do not change and the label has prior approval. For example, if you have a line of "no-msg beef sausages" and that line has already received prior label approval, you can ask for a blanket approval to add pasture-raised to this line because the ingredients are the same.

5b. Provide HACCP process category for the product. See 9 CFR 417.2(b) (1), Example, Heat Treated - shelf stable, Not heat treated-shelf stable etc. Select one.

This is a section that is best to consult with your processor about what to include.

**Please note: In the case of applying for blanket approval for raw cuts and raw ground, you select 03J: Slaughter all Species. Be sure when listing all your cuts for blanket approval in Block 16 that you include raw ground. If you are applying for blanket approval for fresh cut products but not raw ground, you select 03C: Raw Product - not ground. Likewise if you are applying for blanket approval for all ground products but not fresh, you select 03B Raw product - ground. Only select one option in this question.

6a & b. Type of Approval Requested.

Sketch approval is required for Special Claims. So check the sketch approval box.

If temporary approval or extension, insert number of days requested and number of labels on hand. Temporary label approval may be granted as an interim solution in some circumstances, such as if your processor's spice supplier changes ingredients used in your sausages without prior notification. In a case like this, you can ask for a temporary approval to use the existing label even though it does not have the correct ingredients on the label. More details on temporary approval, extensions to temporary approval, and steps to take when asking for temporary approval can be found here in 9 CFR 412.1 Label Approval and in the FSIS Compliance Guideline for Label Approval.

If previous approval, attach copy of application and label. Include specific reason(s) why requesting a temporary or extension and include information required in <u>9 CFR 317.4(f) (1) or 381.132(f) (1)</u> on the continuation sheet. Be sure to include product name and block item.

If a new claim is being added to a product (which is most commonly the case), this answer will likely be "no". However, if an amendment is being made to an existing claim, note it here by checking "yes" and providing the date and information of prior approval. An example of this would be if an ingredient change occurred in a product with a previously approved claim, such as "no-msg sausage."

7a. Area of Principal Display Panel (PDP). The PDP is the entire side of the package to which the label is affixed. See 9 CFR 317.2 (d) and 381.116 (b).

Ask your processor for the total square inches available for the Principal Display Panel (PDP). In the case of a blanket approval application, your processor will know how to fill in this block even when considering the various sized packages that might be listed in a blanket approval scenario.

- 7b. Total available labeling space in square inches for entire package.
- Enter the total allowable space for labeling based on the information provided by your processor. This space refers to both the PDP and the Information Panel (IP) located on side of package. The IP is where additional information can be listed such as ingredients statement, address line, nutrition facts, and safe handling instructions. For further explanation about what the Code of Federal Regulations says about the PDP and IP, please see How to Sell Pastured Meat Products to Grocery Stores via Direct Store Delivery LF-012. Raleigh, NC: The Center for Environmental Farming Systems.
- 8. USDA-AMS Child Nutrition Program Logo. Indicate if the product includes a USDA-AMS Child Nutrition Program Logo.
- 9. Leave Blank. For USDA-AMS use only.
- 10. Special claims, guarantees, or foreign language. Indicate if there are any special claims, guarantees, or foreign language on the label. Check all that apply. If Other Claims is selected, indicate specific claim(s) in space provided.

If adding claims such as "pasture-raised" or "grass-fed" to a label, select Animal Production/Breed/Raising. If the producer has a production claim that is certified such as "American Grassfed Association" then check both Animal Production/Breed/Raising and Certified/Verified. Check all that apply. Reminder: You will need supporting documentation to justify the special claim that you will add at the end of this form. Recommendations for what type of documentation to include is found on p.6 of this sheet under SUPPORTING DOCUMENTATION.

11. Name and Address of Firm. Insert Firm's name and mailing address. Use 2 letter symbol for State. Show postal zip code.

The information that goes here is the same as the information that goes in Box 1. The address used is where the label approval is sent.

12 & 13. Signature and Date of Applicant or Agent. To be signed and dated by the applicant or agent representing the official establishment or plant.

This is the signature of the person associated with the address in Boxes 1 and 11 (either the producer or the processor).

- 14. Leave blank for USDA use only. Conditions Applying to Use of Label or Device. (Any condition, modification or remarks applied to the application when approved are conditions governing use of the approved devices.)
- 15. Product Formula. List the ingredients by percent or weight in order of their predominance. If product consists of several components, e.g., a frozen dinner, list each component separately and indicate the percentage or amount of each component in the product. If additional space is needed, check the box for "Continuation Sheet," and use the Continuation Sheet. Be sure to include the product name and number of the block item. Express all ingredients in the same units, i.e., do not list some in pounds and others in ounces. Check whether weight or percent is used. It is preferred that percentages be used, and the total must equal 100 percent. If weights are used, show in pounds, kilograms or grams. (No gallons, pints, cups, teaspoons, etc.) The total must equal the weights of the individual units. (Example: Crust + Cheese + Sauce + Meat = Total new weight of unit.) DO NOT use fractions. Express as decimals carried to two places, Example: 1-1/4 lbs., show as 1.25 lbs. Example: 3/4 lbs., show as .75 lbs.

The Product Formula refers to the recipe for a multi-ingredient product. So if you are only submitting an application for single ingredient products you can skip this question. Each ingredient is listed in one column while the corresponding ingredient amount is listed by percentage or weight, not both, in the second column. See the below Hot Dogs example. The Formula is written like this:

Product Formula Percentage

Raw Pork	97
Sea Salt, Spices, Evaporated Cane Juice, Paprika, Cherry Powder (Cherry Powder Evaporated Cane Juice), Onion Powder, Natural Flavor (Celery Powder Sea Salt)	2.5
Sheep casing	.5

16. Processing Procedures. Poultry Products provide complete processing procedures as required in 9 CFR 381.134. Meat Products, provide complete processing procedures as required. Note: Approval of the sketch does not convey approval of the processing procedures. If additional space is needed, check the box for "Continuation Sheet," and use the Continuation Sheet.

Be sure to include the product name and number of the block item.

The Processing Procedures refer to how the processing facility handles the product. Here is an example of what an establishment writes for a multi-ingredient product like hot dogs:

"Animal received at Establishment 34060. TA Plant. USDA Humane Handling practiced by facility under inspection by North Carolina Meat & Poultry Inspection (NCDA). Animals slaughter and pass inspection with USDA seal applied before processing. Raw product cut, ground and mixed with seasonings, stuffed into casings and fully cooked to 160 degrees meeting lethality. Product packaged, labeled and frozen."

Here is an example of what an establishment will write for a single ingredient product like pork chops: "Animal received at Establishment 34060. TA Plant. USDA Humane Handling practiced by facility under inspection by North Carolina Meat & Poultry Inspection (NCDA). Animals slaughter and pass inspection with USDA seal applied before processing. Raw product cut. Product packaged, labeled and frozen."

When submitting a blanket approval for single ingredient products, you will want to list them individually here. Don't forget to list raw ground if it is one of your products! Be clear in your explanation. For example, "Here is the list of all the single ingredient, raw cuts pertaining to my Blanket Approval request. This is in continuation from p. 1 Box 5a."

**Please note: You will need to get both the Product Formula and Processing Procedures from your processor.

THE CONTINUATION SHEET

This is the place to list anything there is not enough space to list in Boxes 1-16. Be clear about what is being described and what it pertains to. For example, "Here are the specific reasons why I am requesting temporary approval for my lamb sausage. This is in continuation from p. 1 Box 6a."

SUPPORTING DOCUMENTATION

This is where you include supplemental information such as justifications and affidavits for both multiingredient and single ingredient products. You will use your own pages for this section and attach it to your application when submitting. Put as much detail as possible in this section. For example, it is recommended to address the following in your justification:

- 1. A detailed written description explaining controls for ensuring that the animals are raised in a manner consistent with the meaning of the raising claim that is valid from birth to harvest or the period of raising being referenced by the claim.
- 2. A signed and dated document describing how the animals are raised to support that the claims are not false or misleading. *If you are applying for an animal raising claim, explain in detail what systems are employed such as stocking density, rotational habits, impact on environment, etc.*
- 3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution.
- *The slaughter and/or processing facility has this information.
- 4. A written description of the identification, control, and segregation of nonconforming animals/product. See **Special Claims and the Approval Process for Niche Meat Production** for details on supportive documentation needed when submitting a special claim.

INSTRUCTIONS FOR PREPARATION OF MPIS FORM-11

Please refer to MPIS Form-11 as you read the following detailed information on how to complete this application.

At NCDA inspected facilities, the processor will submit MPIS FORM-11 to their Inspector In Charge (IIC). There are no formal instructions that accompany MPIS Form-11. These instructions are intended to give the farmer a better understanding of what information to provide the processor in order for them to accurately complete this form.

	For Approval (check one)		NORTH CAROLINA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES			
	Final	Sketch	For use until		Meat and Poultry Inspection Division	1
				RECEIVED STAMP	APPROVED STAMP	DISAPPROVED
2	Date Sketch Approved Type of Material: Such as Casing Wrapper, Carton, etc.		10			
5	Formula and Mo	ethod of Preparatio	n			
1	Remarks			11		
	Name of Establ	ichment	P-No.			
	Est. Street/PO Box Address					
	City		Zip			
	Sig. of Est. Rep	resentative	Date			
	Sig. of IIC		Date			
	MPIS Form-11					Complete in tripl

NOTES ABOUT COMPLETING THIS FORM

- 1. Labels with special statements and claims must be sent for approval by the Raleigh NCDA&CS MPID Office prior to use. Special statements and claims are explained in detail in an FSIS compliance guide that is maintained online.
- 2. The Establishment (the processor) will submit this form to the Inspector in Charge (IIC). The inspector then initiates a series of steps that ultimately gets this application to the Raleigh Office for approval.
- 3. Any supporting documentation required (such as documentation to substantiate a claim made on the product label) must be submitted along with MPIS Form-11. What to address in your supporting documentation can be found at the end of these instructions. When MPIS Form-11 is submitted, the supporting documentation is attached using extra pages not included in the form.

1. For Approval

Select "Sketch." Sketch approval is required for Special Claims on labels. There are situations where the sketch label needs minor modifications. In this case, the establishment makes the changes and completes the form by checking "Final" and affixing the corrected label. After the IIC signs off on it, the establishment files both forms together. It does not ¬¬need to be resubmitted to the Raleigh Office.

2. Type of Material

List the material that will be used for your packaging where the label will be applied. You will need to get this answer from your processor.

3. Formula and Method of Preparation

The Formula refers to the recipe for a multi-ingredient product. Each ingredient is listed in one column while the corresponding ingredient is listed by percentage or weight, not both, in the second column.

Let's use Hot Dogs as an example. The Formula may be written like this:

Product Formula Percentage

Raw Pork	97
Sea Salt, Spices, Evaporated Cane Juice, Paprika, Cherry Powder (Cherry Powder Evaporated Cane Juice), Onion Powder, Natural Flavor (Celery Powder Sea Salt)	2.5
Sheep casing	.5

The Method of Preparation refers to how the processing facility handles the product.

Here is an example of what an establishment writes for a multi-ingredient product like hot dogs: "Animal received at Establishment 34060. NCDA Humane Handling practiced by facility under inspection by North Carolina Meat & Poultry Inspection (NCDA). Animals slaughter and pass inspection with NCDA seal applied before processing. Raw product cut, ground and mixed with seasonings, stuffed into casings and fully cooked to 160 degrees meeting lethality. Product packaged, labeled and frozen."

Here is an example of what an establishment will write for a single ingredient product like pork chops: "Animal received at Establishment 34060. NCDA Humane Handling practiced by facility under inspection by North Carolina Meat & Poultry Inspection (NCDA). Animals slaughter and pass inspection with NCDA seal applied before processing. Raw product cut. Product packaged, labeled and frozen."

4. Remarks

This block is reserved for NCDA MPID use.

5. Name of Establishment

This block refers to the name of the processing plant.

**Please note: The processor has both the Formula and The Method of Preparation on file. If more room is needed, attach an extra piece paper and be sure to write in the block, "Please see Attachment 1."

6. P-No.

This is the plant number.

7. Est. Street/PO Box Address and City and Zip

This is the processor's address

8. Sig. of Est. Representative and Date

This is where the processor signs and dates

9. Sig of IIC and Date

IIC stands for Inspector in Charge. This is where the IIC signs and dates.

10. Received Stamp, Approved, Stamp, Disapproved

These blocks are for NCDA MPID internal use only.

11. Large Blank Block

This is where a sketch of the label goes. If it is indeed a sketch and not an actual label, it is helpful to add the measurements. If there is not enough room to add the label or it is just easier, you can attach the label to the application stating clearly what it is. Be sure to write in the block, "Please see Attachment 2."

SUPPORTING DOCUMENTATION

This is where you include supplemental information such as justifications and affidavits for both multi-ingredient and single ingredient products. You will use your own pages for this section, clearly stating this is your supporting documentation and attach it to your application when submitting. Also clearly state which claim you are justifying to include on your label. A list of approvable claims as well as details on supportive documentation needed when submitting a special claim, can be found in the Extension Publication Special Labeling Claims and the Approval Process for Niche Meat Production. Put as much detail as possible in this section. For example, it is recommended to address the following in your justification1:

- 1. A detailed written description explaining controls for ensuring that the animals are raised in a manner consistent with the meaning of the raising claim that is valid from birth to harvest or the period of raising being referenced by the claim.
- 2. A signed and dated document describing how the animals are raised to support that the claims are not false or misleading. This is signed by the farmer/producer. It does not need to be notarized. *If you are applying for an animal raising claim, explain in detail what systems are employed such as stocking density, rotational habits, impact on environment, etc.*
- 3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution.
- *The slaughter and/or processing facility has this information.
- 4. A written description of the identification, control, and segregation of nonconforming animals/product.

Footnotes

1. p. 6 of <u>FSIS Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims</u> <u>for Label Applications</u>

