

- I. SUBJECT: Label Review/Approval Procedures and Submittal Instructions
- II. AUTHORITY: 50 CFR 260.97(c)(12), (13), (15), (16)
- III. PURPOSE: To establish standard procedures for processing fishery product labels submitted by official establishments for NMFS approval; present the new procedures for label review/approval; standardize the temporary approval and disapproval criteria; and identify and define the instances when label approval will be charged to the submitting establishments.
- IV. GENERAL.

A. Title 50 of the Code of Federal Regulations (CFR) requires that establishments contracting for fishery product inspection service obtain NMFS approval of labels prior to use on products packed under Federal inspection, regardless of whether or not they bear official inspection or grade marks. Additionally, "Policy for Advertising Services and Marks", NOAA Inspection Manual 25, Part III, Chapter 1, Section 01, identify additional labeling and advertising of marks and services that must be approved prior to use. Exceptions to this requirement are noted below. Procedures for Child Nutrition (CN) label approval are found in NOAA Inspection Manual 25, Part I, Chapter 3, Section 11.

EXCEPTIONS: This procedure does not apply to products inspected and certified for the Defense Personnel Support Center (DPSC) or other Federal agencies that have specific labeling requirements. However, we recommend that these labels be submitted for review and record-keeping purposes.

B. The Approving Officer, Inspection Services Division, Technical Services Branch, Documentation Approval and Supply Service Section (DASS), Pascagoula, MS, is responsible for administering the Label Review/Approval System and assuring that this system is operational. The authority to approve institutional and case labels is delegated to the Regional Consumer Safety Officers (CSO).

C. Processing specifications for all nonstandardized products shall be submitted for approval concurrently with labels. See

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NOAA Inspection Manual 25, Part I, Chapter 3, Section 08, Product Specifications for Nonstandardized Products. A copy of previously approved specifications must be submitted with each label submittal.

V. SUBMITTAL INSTRUCTIONS.

A. Contracting Party

1. New and revised labels: The processor is required to submit four label proofs and/or finished labels (CN labeling requires five), prior to use, to the assigned Consumer Safety Inspector (CSI)/Consumer Safety Officer (CSO) or supervisory CSO. Proofs of new or revised labels are not required, but are encouraged. Proof review affords establishments the opportunity to obtain information on the compliance of the proof with labeling regulations and may prevent modification to finished labels thus reducing costs.

2. Cancellations: When products are withdrawn from inspection, a completed NOAA Form 89-819, Specification and Label Submittal Action Request, indicating the label approval number, specification number, and approval date is submitted to the assigned CSI/CSO or supervisory CSO for signature. Establishments are encouraged to submit a copy of the original NOAA Form 89-819 on which the label was approved to expedite the process.

3. All submittals must be accompanied by NOAA Form 89-819 through the assigned CSI/CSO, or through the immediate supervisor when the CSI/CSO is not available. (See Attachment 1). It is the responsibility of the submitting establishment to complete the NOAA Form 89-819 prior to submitting the package to the assigned CSI/CSO for review. Establishments are reminded to complete separate NOAA Forms 89-819 for institutional labels, case labels (nonretail), retail labels and CN labels. Only one group, for example retail labels, are to be submitted on a NOAA Form 89-819. Use another NOAA Form 89-819 for submitting CN labels and do likewise for institutional and/or case labels. Further, there are to be no more than four different labels of the same group, e.g., institutional labels, on one NOAA Form 89-819.

**Note:** For purposes of this manual release, retail labels

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are defined as any label bearing mandatory nutrition labeling.

4. In the absence of the assigned CSI/CSO, Block 10, USDC Inspector's signature, may be left blank and a statement placed in Block 13, Remarks, indicating the name of the CSI/CSO's supervisor with whom submittal was discussed and who authorized the submittal. Such submittals will be verified by the Regional Label Approval CSO or the Approving Officer.

5. HACCP-based Inspection Establishments are not required to have the NOAA Form 89-819 signed by a CSI/CSO or supervisory CSO. Such establishments may submit labels, depending on group or type, with the form directly to the Regional Label Approval CSO or the Approving Officer.

6. After review and signature by the assigned CSI/CSO, the establishment is responsible for mailing the submittal package (labels, specifications, and NOAA Form 89-819). Institutional and case labels are mailed to the identified Regional Label Approval CSO, and retail and CN labels are mailed to the Approving Officer.

7. Regional Consumer Safety Officers duty stations

a. Northeast Region

Consumer Safety Officer-Label Review/Approval  
National Marine Fisheries Service  
Northeast Inspection Branch  
One Blackburn Drive  
Gloucester, MA 01930  
Phone (978) 281-9292  
Fax (978) 281-9134

b. Southeast Region

Consumer Safety Officer-Label Review/Approval  
National Marine Fisheries Service  
Tampa Lot Inspection Office

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Attn Label Review  
 1601 North 50th Street  
 Tampa, FL 33619  
 Phone (813) 228-2546  
 Fax (813) 228-2980

c. Western Region

Consumer Safety Officer-Label Review/Approval  
 National Marine Fisheries Service  
 Western Inspection Branch  
 5600 Rickenbacker Road, Bldg. 7  
 Bell, CA 90201  
 Phone (323) 526-7412  
 Fax (323) 526-7417

8. Approving Officer  
 USDC, NMFS  
 Inspection Service Division  
 Technical Services Branch  
 Documentation Approval and Supply Service Section  
 3207 Frederic Street, Suite B  
 P. O. Drawer 1207  
 Pascagoula, MS 39568-1207

B. NMFS CSI or CSO

The assigned CSI or CSO will:

1. assure that only those label proofs and/or finished labels which have been authorized for submittal by a properly designated official of the establishment are sent to the Regional Label Approval CSO or Approving Officer, and that separate NOAA Form 89-819's are completed for retail, CN, institution and case labels;
2. review all label proofs and/or finished labels in accordance with Attachment 2 to assure that the label information agrees with the product represented. Discrepancies should be resolved with the processor. The CSI/CSO will identify any noted discrepancies in Block #13,

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Remarks, on the NOAA Form 89-819, or by a note attached to the form, or directly on one copy of the label submitted, and sign the noted discrepancies;

3. determine that the corresponding specification used to prepare the product has been approved or is being submitted for approval with the label;

4. determine that specifications, and product samples if requested, are submitted in accordance with the instructions contained in Part I, Chapter 3, Section 08;

5. review and sign NOAA Form 89-819 after assuring it is completed in accordance with the instructions, and retain the Field Copy of the form in the office file until approval action has been completed; and

6. return the signed NOAA Form 89-819 to the establishment for submission to the appropriate Regional CSO, or the Approving Officer, DASS.

**Note:** One-Run Approval. The assigned CSI/CSO or supervisory CSO may give one-run approval for a plant to use a label only after reviewing the label in accordance with these instructions and receiving verbal approval from the Regional CSO or Approving Officer. The NOAA Form 89-819 must be completed for immediate submittal to the Regional CSO for the submitting region.

C. Regional Consumer Safety Officer and Approving Officer

1. Label Review and Approval or Temporary Approval or Disapproval.

a. Institutional and case labels will be reviewed by the appropriate Regional Consumer Safety Officer to determine compliance with the Fair Packaging and Labeling Act, Federal Food, Drug and Cosmetic Act, as amended, and other applicable labeling regulations. Retail and CN labels will be reviewed by the Approving Officer to determine compliance with the Fair Packaging and Labeling Act, Federal Food, Drug and Cosmetic Act, as amended, Nutritional Labeling and Education Act, and other applicable labeling regulations.

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b. The Regional Consumer Safety Officer, or the Approving Officer will complete the portion of NOAA Form 89-819 designated "Action Taken," and sign and date the form. Copies will be distributed as follows:

(1) Original and Inspector Copy - To the USDC CSI/CSO stationed at the establishment submitting the labels or proofs. The CSI/CSO will forward the original to the processor, file the Inspector Copy, and discard the Field copy. Copies for HACCP-based Inspection establishments will be returned directly to the submitting establishment.

(2) DASS Office Copy - Retained by the Approving Officer, or submitted to DASS by the Regional Consumer Safety Officer.

(3) Regional Office Copy - Retained by the Regional CSO or will be forwarded to the Regional CSO by DASS.

2. Label Cancellation.

The Regional CSO or the Approving Officer will assure that requests for label cancellation result in proper notation of such labels in the master files. Distribution of NOAA Form 89-819 for cancellation will be the same as that for label approval actions depending on the type label, (retail or nonretail).

VI. LABEL AND PROOF STATUS AS DEFINED BY ACTION TAKEN.

A. Proofs.

1. Proofs submitted for review that comply with the labeling regulations will be "Approved To Print As Is." When the proof is printed, the finished label must be submitted for final approval.

2. Proofs submitted that are not in compliance with the labeling regulations will be "Approved To Print With Changes Noted." When printed with the corrections, finished label must be submitted for final approval.

B. Labels.

1. Labels that are submitted and are in compliance with all labeling laws and regulations will be given a "Final Approval." This approval is good for five years, then the labels must be re-submitted for approval to assure and validate that the labels are current and in use.

2. Labels submitted that are not in compliance with the labeling laws and regulations, standards of identity or other applicable regulations will be given a "Temporary Approval" for minor compliance provided that the noncompliance does not warrant a "Disapproval." (Disapproval is identified below). The temporary approval is granted to allow establishments time to correct the label and re-submit the corrected label.

3. Maximum time limits for "Temporary Approval" are:

- a. four months for flat labels (i.e., those affixed to cartons, packages and cases);
- b. nine months for printed bags; and
- c. twelve months for printed cartons.

4. Temporarily approved labels may be re-submitted for an extension of the temporary approval. The processor must provide information on the stock remaining and the expected usage rate before an extension will be granted. Further, noncompliance may warrant that the label be over-stickered before any additional use of the label is allowed. This condition will be noted on the NOAA Form 89-819, identifying the time-frame for over-stickering.

5. Labels in noncompliance will be given a "Disapproval" for the following reasons:

- a. Labels bearing USDC Inspection Marks that do not accurately convey the degree of inspection effort. Example, a label bearing a PUF I Mark while the product is lot inspected.
- b. Labels bearing USDC Inspection Marks or references to USDC Inspection that are not approved by the "Policy and Guidelines for Advertising USDC Inspection Marks."

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- c. Labels that fail to bear mandatory nutrition labeling and that are not exempt by the regulations.
- d. Labels bearing ingredients statements that do not declare or disclose all ingredients identified by the specification for that product or that fail to declare the use of flavors, artificial colors, preservatives, and/or food additives, or that substantially misidentifies an ingredient to the point that it is false or misleading.
- e. Labels that bear nutrient content claims when the claim does not conform to the regulations for nutrient content claims.
- f. Label that bear net quantity of content statements without metric declaration of the content.
- g. Labels bearing identity statements that do not conform to the standard of identity for that product.
- h. Labels bearing a statement of identity that does not identify the product by common or usual name.
- i. Labels that are required to bear Country of Origin labeling and fail to disclose the country of origin or misrepresent the country of origin.
- j. Labels that utilize an information panel and fail to provide all required information without intervening material (information not required).
- k. Labels that provide nutrition information and fail to declare the correct serving size in relation to the reference serving size, resulting in a misrepresentation of the nutrient levels and erroneous nutrition information.
- l. Labels that contain four or more violations of the requirements contained in the subparts of 21 CFR 101 or other applicable regulations.

#### VII. LABEL REVIEW/APPROVAL CONDITIONS THAT WARRANT BILLING



A. Rate. As established by NOAA Inspection Manual 25, Part I, Chapter 1, Section 16, establishments submitting labels for review/approval may be charged for the time required. The rate for label review/approval is established as Type III, and the minimum charge is established as one half hour.

B. Conditions. The following are the current conditions that warrant charging for label review/approval:

1. Nonapplicant review and opinion on labels.
2. Consultation on labels and specifications for contract and noncontract establishments.
3. Potential clients of the program that have labels reviewed or approved that do not subsequently enter the program.
4. Labels that must be disapproved after the proofs were given initial approval to print as is, or approval to print with changes noted.
5. Labels that are not corrected after submittal of proofs for review.
6. Labels that are given the maximum time (VI.B.3.) on a temporary approval and the establishment requests an extension to continue the use of the label.
7. Fax submission of labels for one-run approvals.

#### VIII. ABBREVIATED LABEL REVIEW/APPROVAL SYSTEM

A. Responding to establishment requests to improve and expedite label approval and to make such establishments more responsible for their labels, the following procedures were developed to follow closely the HACCP-based Inspection Program. Establishments capable of developing labels in compliance with the applicable labeling laws and regulations will have the opportunity to participate in the abbreviated label review/approval system. Such a system will not require pre-approval for all labels by NMFS prior to use.

B. Establishment Requirement Procedures.

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1. Establishments must request in writing, admission to this system. Letters requesting admission are addressed to the Approving Officer (address on page 3 of this manual release).

2. Establishments must provide in the request letter, the name of the person(s) developing the labels for the establishment and include information on the background and qualifications of such person(s) that provide evidence of the individual(s) competency to develop complying labels.

C. NMFS Responsibility.

1. The Approving Officer will review the letters and history of label submittals. History refers to no more than the past year submittals by the requesting establishment.

2. The Approving Officer will provide formal written notice to the establishment indicating acceptance of the establishment into the system.

3. The Approving Officer will notify the appropriate Regional CSO of the establishment's acceptance into the system.

D. System Operation.

1. Labels (retail, institutional, case and CN) must be separated and submitted as identified in V, Submittal Instructions.

2. CN labels will not be included under this system. Food and Nutrition Services (FNS) must pre-approve all CN labels and require NMFS approval prior to their review/approval.

3. Levels.

a. Level III - Thirty labels of each group, excluding CN, must be submitted and undergo a one-of-one review for compliance with all applicable laws and regulations regarding label approval. If all labels of the

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group are in compliance, i.e., no label is disapproved or given temporary approval, the establishment moves to the next higher level (Level II). Establishments under Level III must have labels approved prior to use. If an establishment has labels that are disapproved or temporarily approved, they remain in Level III and repeat the process. An establishment could move to Level II for institutional labels and remain in Level III for retail labels.

b. Level II - Thirty additional labels are reviewed at a one-of-three frequency and are not required to be approved prior to use provided the labels have been submitted to the appropriate review/approval authority. Of the ten labels reviewed, no more than one label considered to be temporarily approved will be permitted in order for the establishment to move to the next higher level (Level I). If one label in the ten is considered disapproved, the establishment falls back to the entry level (Level III). If two labels of the ten reviewed are temporarily approved, the establishment moves back to Level III.

c. Level I - Once the establishment reaches this level, labels will be reviewed at a frequency of one-of-five in lots of 50. If all labels are in compliance or one label in the ten is temporarily approved, the establishment remains in Level I and repeats the process for Level I. If one label is considered to be disapproved, the establishment falls back to Level III. If two labels in the ten reviewed are considered to be temporarily approved, the establishment falls back to Level II.

d. Decision Criteria

Abbreviated Label Review/Approval System			
Level	Labels Reviewed	Total Submitted	Qualifications
III	30 labels 1 of 1 review/group	30/group	If all labels (per group) are in compliance move to Level II. If any labels is disapproved or given Temporary Approval, remain in Level III and repeat.

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II	10 labels 1 of 3 per group	30/group	If all labels (per group) are in compliance or one is given Temporary Approval, move to Level I. If one or more labels is given disapproval, move back to Level III. If two or more labels are given Temporary Approval, move back to entry Level III.
I	10 labels 1 of 5 per group	50/group	If all labels are in compliance or one label is given Temporary Approval, remain in Level I, repeat Level I review. If one or more labels are given disapproval, fall back to Level III. If two or more labels are given Temporary Approval, ball back to Level II and repeat Level II.

4. Removal from the System.

If an establishment falls to Level III twice after entering the system; or if they remain in the entry level after two attempts; or if they fall to a lower level four times; a determination will be made as to the suitability of the establishment remaining in the system.

NOAA FORM 89-819									1. DATE SUBMITTED
U.S. DEPAR TMENT OF COMME RCE									
PRESCRIBED BY INSPECTION MANUAL 25 ADMINISTRATION ( 10-91 )				NATIONAL OCEANIC AND ATMOSPHERIC NATIONAL SEAFOOD INSPECTION PROGRAM				2. PLANT CODE(s)	
<b>SPECIFICATION AND LABEL SUBMITTAL ACTION REQUEST</b>									
<b>INSTRUCTIONS</b> - Please print or complete by typewriter. Submit a set of 5 specifications and/or labels with each product label indicated on form. All copies except field copy are to be submitted to the address below for action. Field copy to be retained by requestor until specifications and/or labels are returned by Approving Officer.						3. PROCESSOR OR PACKER (Name, Address and Phone Number)			
<b>TO:</b> National Seafood Inspection Program Documentation Approval and Supply Services Section 3207 Frederic Street, Suite B P.O. Drawer 1207 Pascagoula, MS 39568-1207						4. DISTRIBUTOR (Name and full address)			
<b>USDC No.</b> (Item 5) to be assigned by Approving Officer. Indicate USDC No. of approved specifications or labels when submitting replacements with minor changes, or when submitting for verification or cancellation. Indicate primary logo, packer or distributor name, or other identification for Item 6. Use numbers only for Item 9: 1 - No. Shield, 2 - Combination Grade A & PUF1, 3 - PUF1 Mark, 4 - Grade A, 5 - Lot Inspected Mark.									
5. USDC NO.		6. PRODUCT IDENTIFICATION (Brand and Identifying numbers if any)			7. COMMODITY (Use official terminology including type, style and size; Indicate in ounces or count/pounds. Enter commodity code and species code)			8 · C O N T E N T O R N E T W T ·	9. SHIELD CODE
LABEL	SPEC.				Comm. Code	Species Code			
10. USDC INSPECTOR (Signature)						11. HAVE SPECIFICATIONS AND/OR LABELS BEEN REVIEWED FOR COMPLIANCE WITH USDC AND FDA REGULATIONS?			
COMPANY OFFICIAL (Signature)						BY INSPECTOR?      BY FIELD INSPECTION OFFICER? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> YES <input type="checkbox"/> NO			
12. ACTION REQUESTED <input type="checkbox"/> LABEL/SPEC. REVIEW <input type="checkbox"/> NEW LABEL SKETCH/PROOF REVIEW <input type="checkbox"/> NEW LABEL APPROVAL (Final) <input type="checkbox"/> NEW SPEC. APPROVAL (FINAL) <input type="checkbox"/> REPLACEMENT SPEC. OR LABEL <input type="checkbox"/> CANCEL APPROVAL <input type="checkbox"/> OTHER (Specify in remarks) <input type="checkbox"/> USDA/FNS (CN) LABEL OR SPECS ACTION <input type="checkbox"/> EXTEND TEMPORARY APPROVAL (Specify reason in remarks)									
NOTE: APPROVAL BY THE USDC IS BASED ON THE INFORMATION SUPPLIED AND DOES NOT IMPLY CONCURRENCE OR ACCEPTANCE BY OTHER FEDERAL, STATE OR LOCAL GOVERNMENTAL AGENCIES UNLESS SPECIFICALLY NOTED, NOR DOES IT RELIEVE THE COMPANY FROM COMPLIANCE WITH OTHER APPLICABLE LAWS, REGULATIONS OR RULINGS. THIS APPROVAL BECOMES VOID IF CHANGES ARE MADE IN THE SPECIFICATION OR LABEL WITHOUT THE CONCURRENCE OF THE USDC APPROVING OFFICER.									

13. REMARKS (Please initial)

TO BE COMPLETED BY APPROVING OFFICE ONLY

PROOF APPROVED FOR PRINTING  AS IS  WITH CHANGES NOTED

APPROVING OFFICER (Signature)

DATE

TEMPORARY APPROVAL EXPIRES \_\_\_\_\_

FINAL APPROVAL  DISAPPROVED  CANCELLED

EXTENDS APPROVAL  REVIEWED

USDA/FCS USE ONLY

SKETCH/PROOF

LABEL

CONCURRENCE

NON-CONCURRENCE

USDA APPROVAL (Signature)

DATE

LABEL CHECKLIST