

(2) Moisture content—"Moisture—Official Final Action," section 16.174.²

(d) *Nomenclature.* The name of the food is "Dry cream." The name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label, in letters not less than one-half of the height of the letters used in such name:

(1) The phrase "Contains — percent milkfat", the blank to be filled in with the whole number closest to the actual fat content of the food.

(2) The word "sweetened" if no characterizing flavoring ingredients are used but nutritive carbohydrate sweetener is added.

(e) *Label declaration.* Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

Any person who will be adversely affected by the foregoing regulation may at any time on or before June 8, 1978, submit to the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date: Except as to any provisions that may be stayed by the filing of proper objections, compliance with this final regulation, including any required labeling changes, may begin July 10, 1978, and all products

initially introduced into interstate commerce on or after July 1, 1979 shall fully comply. Notice of the filing of objections or lack thereof will be published in the FEDERAL REGISTER.

(Secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)).)

Dated: April 28, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

NOTE.—Incorporation by reference approved by the Director of the Office of the Federal Register on March 11, 1976 and is on file in the Federal Register Library.

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[4110-03]

[Docket No. 75P-0104]

PART 161—FISH AND SHELLFISH

Standard of Identity, Fill of Container Standard for Canned Shrimp

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document establishes a standard of identity and revises the fill of container standard for canned shrimp. In response to petitions filed by the American Shrimp Canners Association (ASCA), this action is taken to comply, to the extent practicable, with the provisions of the Codex Alimentarius.

EFFECTIVE DATE: July 1, 1979 for all products initially introduced into interstate commerce on or after this date. Voluntary compliance: July 10, 1978. Objections by: June 8, 1978.

FOR FURTHER INFORMATION CONTACT:

Harold Salwin, Bureau of Foods (HFF-416), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-8531.

SUPPLEMENTARY INFORMATION: In response to two petitions filed by the American Shrimp Canners Association (ASCA), P.O. Box 50774, New Orleans, La. 70150, the Food and Drug Administration (FDA) published in the FEDERAL REGISTER of April 19, 1976 (41 FR 16470) a proposed standard of identity for canned shrimp (21 CFR 161.173(a)) and revision of the fill of container standard (21 CFR 161.173(c), previously codified as § 36.3, and recodified at 42 FR 14464, Mar. 15, 1977) for the purpose of adopting, to the extent practicable, the provisions of the Codex standard for canned shrimp or prawns. The preamble to the proposal included the Codex standard,

the regulations proposed by ASCA, and the Commissioner's comments.

In response to the proposed standard of identity, the Commissioner received 12 letters, each containing 1 or more comments, from Pacific Northwest canned shrimp packers, ASCA, and the National Food Processors Association (NFPA) (formerly the National Canners Association). No comments were received on the proposed revision of the fill of container standard. After the 90-day comment period, ASCA requested a meeting with FDA. FDA personnel and representatives of ASCA met on September 22, 1976. Subsequently, the Commissioner received a number of comments from ASCA and NFPA proposing amendments to the Commissioner's April 19, 1976 proposal. The amendments pertained to definitions of styles of shrimp, size designations, and tolerances for improperly cleaned shrimp.

Copies of all comments and memorandums of meetings and telephone conversations are on file with the Hearing Clerk (HFC-20), Food and Drug Administration. The following regulations adopt to the extent practicable the provisions of Codex since the Commissioner concludes that to do so will benefit consumers and facilitate international trade.

DISCUSSION OF COMMENTS

DEFINITIONS

1. Several comments stated that the proposed requirement that the packing medium be added in sufficient volume to cover the shrimp was too stringent. One comment suggested that rather than using the proposed wording to accomplish an adequate liquid fill, a minimum net weight for each can size would suffice. Two comments stated that it is almost impossible to cover the smaller North Pacific shrimp in an aqueous packing medium and still achieve the desired drained weight and proper vacuum. The NFPA stated that obtaining a proper drained weight and providing necessary head space will often result in portions of one or more shrimp extending above the surface of the liquid in the container. The NFPA suggested that the wording in this provision be changed to require packing medium "in sufficient volume to fill the interstices and permit proper processing in accordance with good manufacturing practice."

The Commissioner believes that NFPA's suggested language better defines his intent and adequately addresses the concerns expressed in other comments. Therefore, § 161.173(a)(1) is revised accordingly.

2. Two comments objected to the words "... under good manufacturing practice ..." in connection with processing to remove shells, legs, and antennae. They suggested "commercial"

in place of "manufacturing." One of the comments stated that the requirement "is not specific as to who is to determine and by what standards such determination would be made as to the extent practicable under good practices of production."

The Commissioner concludes that the word "manufacturing" is consistent in language with other food regulations promulgated by FDA and the intent expressed in the Codex standard 3.3.4. The Commissioner considers the standards of good manufacturing practice, as defined in 21 CFR Part 110, sufficient criteria, and that compliance with such standards is determined by what is normal good manufacturing practice in the industry. Therefore, he is retaining the original language in § 161.173(a)(1).

3. Three comments claimed that since the proposed definition for cleaned style shrimp explicitly states that the back of the shrimp must be deliberately cut open and the dorsal tract removed, Pacific Northwest shrimp could only be considered as regular style. It was stated that shrimp canned in the Pacific Northwest have a vein near the surface which is "cleaned" during the peeling process without cutting the back open. The comments stated that shrimp species canned in the Pacific Northwest may not exhibit visible dark veins even though the shrimp are not deveined in the manner which was proposed for "cleaned" style shrimp. The comments indicated that Pacific Northwest canners did not believe they could differentiate by labeling their canned shrimp from other canned shrimp that contain dark veins because of the definition proposed. The comments also suggested that the words "deveined" and "cleaned" are not synonymous as was stated in the proposal. It was further suggested that the word "cleaned" could be removed from the standard. The comments recommended three styles of canned shrimp characterized by the presence or absence of visible dark veins. The comments suggested that the following three styles be provided and designated on the label:

(a) "Visible dark veins" or "dark veined" when the shrimp contain dark veins.

(b) "No dark veins" when the shrimp do not exhibit dark veins.

(c) "Deveined" or, when appropriate, "mechanically deveined" when the shrimp have been split open and the dorsal tract removed.

In a letter dated March 9, 1977, the NFPA, claiming to represent a consensus of the entire shrimp canning industry, proposed that the following three specific optional styles of whole canned shrimp be incorporated in the proposed regulations: "(1) 'regular' style shrimp are those that have been

peeled and subsequently canned without intentional removal of the dorsal tract; (2) 'cleaned' style shrimp are those that have been peeled and subsequently canned and for which the dorsal tract is not readily visible; (3) 'deveined' style shrimp are those that have been peeled and subsequently canned and have had the dark dorsal tract removed by deliberate cutting action." Although not specifically stated in the March 9 letter, the Commissioner assumes that NFPA intended the first word or name of the last two styles to be available for use on the label.

The Commissioner does not agree that shrimp which contain dark veins need to be labeled as "dark veined" or "visible dark veins" since this style has historically been called "shrimp." Moreover, such shrimp can be differentiated from the canned shrimp which do not contain dark veins by label identification of the latter as "deveined" if the shrimp have, in fact, been deveined, or with such words as "contains no dark veins," or some other such truthful statement. With regard to whether the word "mechanically" should be declared in conjunction with "deveined", the Commissioner concludes that "deveined" is sufficient, but he would not object to packers including the word "mechanically" if the shrimp have, in fact, been deveined by machine. He also does not agree that the word "cleaned" needs to be deleted from the standard. Through long usage in both the frozen and canned shrimp industries, the words "cleaned" and "deveined" have become synonymous and are used interchangeably to describe shrimp which have had the back split open and the dorsal tract removed. Furthermore, the Commissioner believes that consumers of canned shrimp also recognize "cleaned" as meaning "deveined". The Commissioner concludes that it would be improper to follow the NCA suggestion which would allow products that have not been deveined by deliberate cutting action to be called "cleaned." Therefore, he is retaining in the final regulation the optional designations of style as originally proposed. To alleviate possible confusion, he has added to the regulation provisions which recognize a style of shrimp which have no readily visible dark vein, even though the shrimp have not been deveined by deliberate cutting action. In paragraph (a)(5)(iii) the regulation provides for the optional labeling of this style with the words "contains no dark veins" or their equivalent. He believes that these provisions allow packers of canned shrimp to differentiate their products adequately without consumer confusion. He points out that the language defining styles has been modified by deleting references to canning and peeling.

The Commissioner states that these aspects belong more appropriately in the definition paragraph (a)(1). He has also deleted, as superfluous, the sentence "By long usage, the terms, 'cleaned' and 'deveined' are synonymous." The Commissioner also notes that the proposed requirement that canned shrimp be of similar size has been deleted, because it is his opinion that the standard should provide for packs of mixed, as well as similar, size.

TOLERANCES

4. Two comments stated that the requirement in § 161.173(a)(1) that products be free of heads is absolute and does not take into account the unavoidable possibility that, particularly with small shrimp, an occasional head will find its way into the final product even when the best manufacturing practices are followed. One of the comments suggested that the wording be revised to require the product to be free "to the extent practicable under good manufacturing practice, from heads, shells, legs, and antennae." The second comment suggested similar language and stated that all exoskeleton components, including heads, should be treated equally.

The Commissioner concludes that the comments, if accepted, would sanction the possibility and likelihood of heads in the product. That is not his intent. The Commissioner's opinion is that in most instances the head comprises almost one half of the animal and can be easily removed from the product flow when passed by an inspection line. Further, since the provision adopts the Codex standard, the Commissioner considers the provision reflective of world-wide practice and the language adequate, since it expresses what is technologically feasible. Therefore, he is retaining the original language.

5. One comment objected to the 5 percent by weight tolerance for improperly cleaned shrimp and stated that the standard should incorporate the schedule of tolerances which ASCA proposed in its original petition, namely, 5 percent for extra large (jumbo) and large sizes, 10 percent for medium and small shrimp, and 15 percent for tiny and broken shrimp. ASCA claims that such allowances are necessary because they more realistically represent the cleaning effectiveness of mechanical deveining equipment that is essential for economical processing of the smaller sized shrimp. A second comment described the 5 percent tolerance for improperly cleaned shrimp as unrealistic for tiny shrimp. It also stated that the 5 percent tolerance "is confusing, especially when related to table II allowance of 15 percent for tiny shrimp."

The Commissioner is retaining the 5 percent tolerance for improperly pre-

pared shrimp for all sizes, since that tolerance is required in Codex and therefore represents the reasonable conclusion of experts world wide. The Commissioner points out that table II in §161.173(a)(5)(iv) lists tolerances for broken shrimp in canned whole shrimp rather than tolerances for improperly prepared shrimp.

6. One comment on the proposed definition and tolerances for broken shrimp suggested that the rules be applied to sizes "small" and larger but not "tiny." The comment stated that the west coast tiny shrimp pack consists of a mixture of 1-year old, 2-year old, 3-year old, and in some areas 4-year old shrimp. Also, the comment stated that it is almost impossible for an expert to spot the difference between a 1-year old whole shrimp and a broken shrimp or to determine the number of segments. The comment suggested that the regulation state that 1-year old and 2-year old tiny Pacific pink shrimp should not be considered as broken shrimp.

The Commissioner does not see any reason to change the regulation and points out that whole shrimp, regardless of size, would not be considered as broken shrimp.

The Commissioner notes that when size of shrimp is not identified on the label, it would be necessary in each instance to determine the size in order to enforce the labeling provisions for broken shrimp. He has therefore defined in §161.173(a)(5) the conditions which require such labeling for tiny shrimp and for all other shrimp whether of similar or mixed sizes.

SIZE DESIGNATIONS

7. ASCA proposed amending the size designations in a manner which ASCA claims will reduce consumer confusion. It should be noted that the size designations proposed in the April 19, 1976 FEDERAL REGISTER are identical with those in Codex and in the identity standard originally proposed by ASCA. The ASCA comments compared tiny size shrimp from the Gulf Coast, which number in count from 17 to 27 shrimp per ounce to tiny shrimp from the Pacific Northwest which number 22 to 56 per ounce. It was stated that the consumer, when using these variants of "tiny," must be confused by the wide spread in count within the same size designation. ASCA also stated that competition from the fresh, frozen, and breaded shrimp industries for the larger sizes of shrimp has left only the medium, small, and tiny sizes available in any quantity to canners in the warm water areas, and that these sizes represent over 90 percent of the Gulf Coast pack. ASCA recommended changing the lower

limit for "tiny" from 17.0 to 22.2 shrimp per ounce. As a result of this proposed size change, ASCA recommended that the limits of the "small" classification change from the range 9.0 to 17.0 per ounce to 13.0 to 22.2 per ounce. ASCA also stated that the "medium" classification, in order to keep its proper place in the size spectrum and give consumers a real choice of the sizes actually produced, should be changed to reflect its proper midposition in the total pack—namely, from the range 5.0 to 9.0 per ounce to 7.0 to 13.0 per ounce. ASCA pointed out that slight modifications of the larger size designations would be necessary based on the same reasoning; ASCA also stated that very few of these sizes are packed as canned shrimp. ASCA claimed that the realignment of sizes resulting from the adoption of these proposed changes would make the size designations more useful to consumers in purchasing the kinds of shrimp they prefer, would encourage uniformity and consistency in commercial practice, and would allow the canned shrimp industry to remain viable and competitive.

In a related matter, ASCA also commented on the proposed size designations for deveined shrimp. The com-

ment explained that the greater number of shrimp per ounce reflects an 8 percent tolerance to allow for loss in weight when the shrimp are deveined. ASCA claims that the 8 percent tolerance is no longer appropriate because it was adopted as a portion of the industry grade standards in 1954 when deveining was done by hand. Mechanical deveining came into widespread use in the 1960's. According to ASCA, industrial experience and experimental work carried out under commercial operating conditions demonstrate that the loss is greater with mechanical deveining, and that it increases as the size of the shrimp decreases. ASCA submitted data purporting to demonstrate these losses for four sizes of shrimp, and stated that the minimum loss factors are 10 percent for jumbo and large sizes, 11 percent for medium, and 12 percent for small and tiny size shrimp.

ASCA presently proposes the following size designations which reflect the considerations in the preceding paragraphs. These size designations were endorsed in the March 9, 1977 comment from NFPA, which claimed to represent the views of the entire shrimp canning industry.

SIZE DESIGNATIONS OF CANNED SHRIMP

Size	Number of shrimp per 1 oz (28.4 g) of drained product		Number of shrimp per 100 g (3.5 oz) of drained product	
	Regular	Deveined	Regular	Deveined
Jumbo.....	Less than 5.....	Less than 5.5.....	Less than 17.5.....	Less than 19.3.....
Large.....	5 or more but less than 7.....	5.5 or more but less than 7.8.....	17.5 or more but less than 24.5.....	19.3 or more but less than 27.3.....
Medium.....	7 or more but less than 13.....	7.8 or more but less than 14.4.....	24.5 or more but less than 45.5.....	27.3 or more but less than 50.4.....
Small.....	13 or more but less than 22.2.....	14.4 or more but less than 24.9.....	45.5 or more but less than 77.7.....	50.4 or more but less than 87.2.....
Tiny or cocktail...	22.2 or more.....	24.9 or more.....	77.7 or more.....	87.2 or more.....

As stated in ASCA's comments, two separate issues of concern are:

(a) An inconsistency in the number of shrimp constituting the size designation "tiny" which ASCA proposes to correct by restructuring all of the size designations as displayed vertically in the foregoing table in the columns headed "regular."

(b) The allowance for loss of shrimp flesh during the deveining process as displayed by the differences horizontally between the counts for "regular" and "deveined" for any given size designation.

First, the Commissioner recognizes that variance exists in counts per ounce of canned shrimp labeled as "tiny," primarily because of the species utilized. However, he has no evidence that consumers are "confused" as ASCA claims, since no substantiating data were submitted to support such a contention. Furthermore, the

Commissioner maintains that ASCA's proposed restructuring of the entire size designation table to alleviate the differences stemming from variances within counts for "tiny" canned shrimp is inappropriate. The effect of the suggested change would be that "medium" shrimp would be smaller, for example, than what a consumer receives today. Second, the Commissioner considers the data submitted as insufficient to determine whether weight loss factors should be increased to account for mechanical deveining. Therefore, he is retaining the size designation table as proposed. The Commissioner advises that this decision regarding the above proposal by ASCA is without prejudice to the filing of future petitions to amend the standard. Such petitions should be substantiated by sound, scientifically determined findings and facts.

ASCA, in commenting on its proposed amendments to the size designations, stated that if more clarification is needed, "the label could show the count per ounce in conjunction with adjective descriptions." Even though the Commissioner is not adopting ASCA's recommended size designations, a declaration of count per ounce may have merit. If later information indicates that a label declaration of count per ounce will benefit consumers, the Commissioner, at that time, will take appropriate action to propose such a requirement. The Commissioner will give careful consideration to any petition proposing such a requirement. In any event, he does not consider it appropriate to provide for such a requirement in this final regulation, since to do so now would not provide other interested persons an opportunity for comment.

LABELING

8. Two comments took exception to the mandatory labeling of shrimp which number more than 17 per ounce as "tiny" or "tiny cocktail." They contended that the term "tiny" or "tiny cocktail" should be treated as an optional size requirement in a manner similar to the other size designations. One of the comments stated that it could not agree with the view cited in FDA Compliance Policy Guide 7108.3 in support of the mandatory requirement. The comment gave the following reason: "The size designations, 'jumbo,' 'large,' 'medium,' and 'small' were defined in about 1935 when FDA was operating a continuous seafood inspection service. Very small or tiny shrimp began to be packed with the development of mechanical peelers in the 1940's, and that size designation was used on labels very early. In the intervening years, the consumer has become equally familiar with all of the size designations currently in use."

In the absence of any supporting data, the Commissioner is of the opinion that his view on the mandatory label declaration of the size "tiny" is still valid. Therefore, he is not making the suggested change. Upon further examination of the table of proposed size designations, the Commissioner notes that the smallest size shrimp were identified as "tiny or cocktail." Although that designation was consistent with ASCA's proposal, it did not represent the Commissioner's intent. The Commissioner considers the word "cocktail" as descriptive of a use for the food and applicable to various sizes of shrimp, not just "tiny." Moreover, Codex does not recognize "cocktail" as an alternative for "tiny." Since the term "cocktail" as applied to shrimp is not an acceptable substitute for the word "tiny," the Commissioner has deleted the word "cocktail" from the table of size designations in the

regulation set out below. There is no objection to the use of the word "cocktail" in the labeling of canned tiny shrimp, provided the label bears the word "tiny" as required by § 161.173(a)(5)(v) of the regulation.

9. One comment suggested that the word "prawns" as provided for in Codex be incorporated into the standard as an optional name for the food.

The Commissioner concludes that the food may appropriately be labeled with the word "prawns" in conjunction with the name "shrimp" when the size is large or extra large as defined in § 161.173(a)(5)(iv). He has provided for such labeling in § 161.173(a)(5)(i). The Commissioner advises that he is limiting the use of the word "prawns" to maintain consistency between this regulation and a similar provision in the standard of identity for frozen raw breaded shrimp (21 CFR 161.175).

10. One comment requested that the standard include a provision to require label declaration if canned shrimp are prepared from frozen shrimp. The comment also stated that if frozen shrimp are imported for canning, the label cite the country of origin. The comment stated that these types of pack are of poorer quality than fresh packed shrimp.

The Commissioner is not incorporating the suggested provision, since he has no supporting data indicating that shrimp canned from frozen raw stock are inferior in quality. Moreover, the regulation below is intended to establish a standard of identity and not quality. The Commissioner would not object to label declarations which identify raw material as fresh or frozen or as to country of origin if such declarations are factual and not misleading.

OPTIONAL INGREDIENTS

11. Comments suggested that citric acid should be included among the permitted optional ingredients.

The Commissioner advises that the provision for organic acids includes citric acid.

12. One comment stated that since the proposed standard permits the use of spices or spice oils or spice extracts, the standard should also permit the capture and adding back of natural shrimp oil that leaches out during preliminary stages of processing. The comment requested that natural shrimp oil be included as an optional ingredient.

The Commissioner has made inquiries regarding this request, and he understands that the capture and adding back of shrimp oil is not regular industry practice. Further, he is not aware of consumer or industry interest in providing for the addition of shrimp oil to canned shrimp, and has not made the provision in the regulation

set out below. Any interested persons who have information demonstrating a need for the addition of shrimp oil to canned shrimp may submit a petition documenting the fact that such use would promote honesty and fair dealing in the interest of consumers.

13. One comment stated that sodium tripolyphosphate (STP) should be allowed as an acceptable additive to canned shrimp. The comment stated that industry studies have failed to reveal any discernible weight change in canned shrimp treated with STP.

The Commissioner reiterates his viewpoint, as expressed in the preamble to the April 19, 1976 proposal, that STP is generally known to cause water uptake and retention in various protein foods. In the absence of data demonstrating that the use of STP in canned shrimp does not result in water uptake and retention, the Commissioner does not consider STP to be a suitable ingredient for this food and is not providing for its use in the regulation set out below.

The Commissioner also points out that the standard of identity set forth below is organized in a format different from that which was proposed. He is of the opinion that the revision, which conforms with other food standards recently promulgated by FDA, improves the clarity of the regulation. He has also made editorial changes in the provisions relating to sample unit and defective samples in paragraph (a)(6)(i) (d) and (e) of the identity standard and paragraph (c)(2) of the fill of container standard. The principal effect of these changes is to extend the application of the sampling and acceptance procedure to sample units that fail to meet the labeling requirements for broken shrimp.

After considering the comments received and other relevant information, the Commissioner concludes that it will promote honesty and fair dealing in the interest of consumers to establish a definition and standard of identity for canned shrimp and to revise the fill of container standard for canned shrimp as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046, as amended, 70 Stat. 919 (21 U.S.C. 341, 371(e))) and under authority delegated to him (21 CFR 5.1), 21 CFR 161.173 is amended by revising the section heading, adding a new paragraph (a) *Identity*, and revising paragraph (c) *Fill of container* as follows:

§ 161.173 Canned wet pack shrimp in transparent or nontransparent containers.

(a) *Identity*. (1) Canned wet pack shrimp is the food consisting of the processed meat of peeled shrimp, free of heads and, to the extent practicable under good manufacturing practice,

free of shells, legs, and antennae; in one or any combination of species enumerated in paragraph (a)(2) of this section; prepared in one of the styles specified in paragraph (a)(3) of this section, in sufficient water or other suitable aqueous packing medium to fill the interstices and permit proper processing in accordance with good manufacturing practice. Canned shrimp may contain one or more of the optional ingredients specified in paragraph (a)(4) of this section. It is packed in hermetically sealed transparent or nontransparent containers and so processed by heat as to prevent spoilage.

(2) The species of shrimp that may be used in the food are of the families: Penaeidae, Pandalidae, Crangonidae, and Palaemonidae.

(3) Styles. Canned shrimp is prepared in one of the following styles:

(i) Shrimp with readily visible dark vein (dorsal tract, back vein, or sand vein).

(ii) Deveined shrimp containing not less than 95 percent by weight of shrimp prepared by removing the dark vein from the first five segments by deliberate cutting action.

(iii) Shrimp, other than "deveined" as described in paragraph (a)(3)(ii) of this section, containing not less than 95 percent by weight of shrimp with no readily visible dark vein within the first five segments.

(iv) Broken shrimp, consisting of less than four segments and otherwise conforming to one of the styles described in paragraph (a)(3)(i), (ii), or (iii) of this section.

(4) Optional ingredients. The following safe and suitable optional ingredients may be used:

- (i) Salt.
- (ii) Lemon juice.
- (iii) Organic acids.
- (iv) Nutritive carbohydrate sweeteners.

(v) Spices or spice oils or spice extracts.

(vi) Flavorings.

(vii) Sodium bisulfite.

(viii) Calcium disodium EDTA (calcium disodium ethylene-diaminetetraacetate), complying with the provisions of § 172.120 of this chapter.

(5) Labeling. (i) The name of the food is "shrimp" or "shrimps." The word "prawns" may appear on the label in parentheses immediately after the word "shrimp" or "shrimps" if the shrimp are of large or extra large size as designated in paragraph (a)(5)(iv) of this section.

(ii) When the food is of the style described in paragraph (a)(3)(ii) of this section, the words "cleaned," "cleaned (deveined)," or "deveined" may be declared on the label.

(iii) When the food is of the style described in paragraph (a)(3)(iii) of this section, the words "contain no dark

veins" or their equivalent may be declared on the label.

(iv) When the food is whole shrimp within a size range designated in Table I as "extra large," "large," "medium," or "small" and does not contain

broken shrimp as defined in paragraph (a)(3)(iv) of this section in excess of the amount listed in Table II for the applicable size, the appropriate size designation may be declared on the label.

TABLE I

Size	Number of shrimp per 28.4 g (1 oz) of drained product		Number of shrimp per 100 g (3.5 oz) of drained product	
	Other than deveined style	Deveined style	Other than deveined style	Deveined style
Extra large or jumbo.	Less than 3.5.....	Less than 3.8.....	Less than 12.3.....	Less than 13.4.
Large	3.5 to 5 inclusive.....	3.8 to 5.4 inclusive.....	12.3 to 17.7 inclusive.	13.4 to 19.1 inclusive.
Medium	More than 5 but not more than 9.	More than 5.4 but not more than 9.8.	More than 17.7 but not more than 31.8.	More than 19.1 but not more than 34.6.
Small	More than 9 but not more than 17.	More than 9.8 but not more than 18.4.	More than 31.8 but not more than 60.	More than 34.6 but not more than 65.3.
Tiny	More than 17	More than 18.4	More than 60	More than 65.3.

TABLE II

Size	Maximum percent by weight of broken shrimp*
Extra large or jumbo	5
Large	5
Medium	5
Small	10
Tiny	15

*Grams of broken shrimp per 100 g of cutout weight as determined in § 161.173(c) of this section.

(v) When the food consists of tiny shrimp, as designated in Table I in paragraph (a)(5)(iv) of this section and does not contain broken shrimp as defined in paragraph (a)(3)(iv) of this section in excess of 15 percent by weight, the name of the food on the label shall be accompanied by the word "tiny" in type size equal to that used in the name of the food.

(vi) When the food consists of tiny shrimp, as designated in Table I in paragraph (a)(5)(iv) of this section and contains more than 15 percent by weight of broken shrimp as defined in paragraph (a)(3)(iv) of this section, the name of the food on the label shall be accompanied by the word "broken" or "pieces" rather than the word "tiny," in type size equal to that used in the name of the food.

(vii) When the food consists wholly or in part of sizes other than tiny, as designated in Table I in paragraph (a)(5)(iv) of this section and contains more than 10 percent by weight of broken shrimp as defined in paragraph (a)(3)(iv) of this section, the name of the food on the label shall be accompanied by the word "broken" or "pieces" in type size equal to that used in the name of the food.

(viii) The name of the food shall in-

clude a declaration of any flavoring that characterizes the food, as specified in § 101.22 of this chapter, and the term "spiced" if spice characterizes the food.

(ix) Each of the ingredients used shall be declared on the label as required by the applicable sections of part 101 of this chapter.

(6) Sampling and acceptance procedure. A lot is to be considered acceptable when the number of defectives does not exceed the acceptance number in the sampling plans given in paragraph (a)(6)(ii) of this section.

(i) Definitions of terms to be used in the sampling plans in paragraph (a)(6)(ii) of this section are as follows:

(a) *Lot*. A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(b) *Lot size*. The number of primary containers or units in the lot.

(c) *Sample size (n)*. The total number of sample units drawn for examination from a lot.

(d) *Sample unit*. A container, the entire contents of a container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for the examination or testing as a single unit.

(e) *Defective*. Any sample unit shall be regarded as defective when it fails to meet the minimum requirements in paragraph (a)(3) (ii) or (iii) of this section for the applicable style, when it exceeds the tolerances in paragraph (a)(5)(iv) of this section for the applicable size, or when the labeling fails to meet the requirements of paragraph (a)(5) (v), (vi), or (vii) of this section of the applicable size.

(f) *Acceptance number (c)*. The maximum number of defective sample units

permitted in the sample in order to consider the lot as meeting the specified requirements.

(g) *Acceptable quality level (AQL).* The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

(ii) Sampling plans:

Acceptable quality level 6.5

Lot size (primary containers)	Size of container	
	Net weight equal to or less than 1 kg (2.2 lb)	Net weight greater than 1 kg (2.2 lb) but not more than 4.5 kg (10 lb)
	<i>n</i>	<i>c</i>
4,800 or less.....	13	2
4,801 to 24,000.....	21	3
24,001 to 48,000.....	29	4
48,001 to 84,000.....	48	6
84,001 to 144,000.....	84	9
144,001 to 240,000.....	126	13
Over 240,000.....	200	19

	<i>n</i>	<i>c</i>
2,400 or less.....	13	2
2,401 to 15,000.....	21	3
15,001 to 24,000.....	29	4
24,001 to 42,000.....	48	6
42,001 to 72,000.....	84	9
72,001 to 120,000.....	126	13
Over 120,000.....	200	19

n = Number of primary containers in sample.
c = Acceptance number.

(b) [Reserved]

(c) *Fill of container.* (1) The standard of fill of transparent or nontransparent containers for canned wet pack shrimp is a fill such that the cut-out weight of shrimp taken from each container is not less than 60 percent of the weight of the water required to fill the container. The weight of the water required to fill the container is determined by the general method provided in § 130.12(a) of this chapter. Cut-out weight is determined by the following method: Keep the unopened canned shrimp container at a temperature of not less than 68° nor more than 75° Fahrenheit for at least 12 hours immediately preceding the determination. After opening, distribute the shrimp evenly over the meshes of a circular sieve that has been previously weighed. The diameter of the sieve is 20.3 centimeters (8 inches) if the quantity of the contents of the container is less than 1.36 kilograms (3 pounds), and 30.5 centimeters (12 inches), if such quantity is 1.36 kilograms (3 pounds) or more. The bottom of the sieve is woven-wire cloth that complies with the specifications for such cloth set forth as a 2.36-millimeter (No. 8) sieve in the "Definitions of Terms and Explanatory Notes," p. XVI of the "Official Methods of Analysis of the

Association of Official Analytical Chemists," 12th ed., 1975.¹ Without shifting the material on the sieve, incline the sieve at an angle of approximately 17° to 20° to facilitate drainage. Allow the shrimp to drain for 2 minutes, measured from the moment the product is poured onto the sieve. Weigh the sieve and the drained shrimp. The weight so found, less the weight of the sieve, shall be considered to be the cut-out weight of the shrimp.

(2) Sampling and acceptance procedure: A container that falls below the requirement for minimum fill prescribed in paragraph (c)(1) of this section is considered a "defective." Determine compliance with paragraph (c)(1) of this section as specified in paragraph (a)(6) of this section except that the sample unit shall be the entire contents of the container.

(3) If canned wet pack shrimp in transparent or nontransparent containers falls below the applicable standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill provided in § 130.14(b) of this chapter, in the manner and form therein specified.

Any person who will be adversely affected by the foregoing regulation may at any time on or before June 8, 1978, submit to the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

¹Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

Effective date. Except as to any provisions that may be stayed by the filing of proper objections, compliance with this final regulation, including any required labeling changes, may begin July 10, 1978, and all products initially introduced into interstate commerce on or after July 1, 1979, shall fully comply. Notice of the filing of objections or lack thereof will be published in the FEDERAL REGISTER.

NOTE.—FDA has determined that this document does not contain a major proposal requiring preparation of an economic impact statement under Executive Orders 11821 and 11949 and OMB Circular A-107. A copy of the economic impact assessment is on file with the Hearing Clerk at FDA.

(Secs. 401, 701, 52 Stat. 1046, 1055-1056, as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 341, 371).)

Dated: April 28, 1978.

WILLIAM F. RANDOLPH,
 Acting Associate Commissioner
 for Compliance.

[FR Doc. 78-12391 Filed 5-8-78; 8:45 am]

[4110-03]

[Docket No. 77N-0038]

FOOD ADDITIVES AND SUBSTANCES GENERALLY RECOGNIZED AS SAFE CAPRYLIC ACID

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that caprylic acid is generally recognized as safe (GRAS) as a direct and indirect human food ingredient. The safety of this ingredient has been evaluated under the comprehensive safety review being conducted by this agency.

EFFECTIVE DATE: June 8, 1978.

ADDRESS: Written objections may be sent to the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of June 14, 1977 (42 FR 30390), a proposal was published to affirm that caprylic acid is generally recognized as safe for use as a direct and indirect human food ingredient. The proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review on caprylic acid, a report of the mutagenic test for the ingredient, and the report of the Select Committee on GRAS Substances (hereafter referred to as the Select Committee) have been made available for public review in the office of the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. Copies of these documents have also been made available for public purchase from the National Technical Information Service as announced in the proposal.

In addition to proposing to affirm the GRAS status of caprylic acid, the Commissioner gave public notice that he was unaware of any prior-sanctioned food ingredient use for this ingredient other than for the proposed conditions of use. He advised that persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, shall submit proof of those sanctions so that the safety of the prior-sanctioned uses could be determined, and he proposed to approve prior-sanctioned uses of caprylic acid in appropriate regulations under part 181 (21 CFR Part 181), provided the prior-sanctioned use could be affirmed as safe on the basis of information and data now available to him. He also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned use for caprylic acid were submitted in response to the proposal. Therefore, in accordance with that proposal, any right to assert a prior sanction for a use of caprylic acid under conditions different from those set forth in this regulation has been waived.

One comment was received in response to the proposal. The comment criticized the proposal for affirming the GRAS status of caprylic acid as an indirect food substance for a single specific use (i.e., in cheese wraps), while affirming the GRAS status of the substance for direct food use as a flavoring ingredient. The comment concluded that consumer exposure through other possible indirect food uses could not possibly match exposure from use as a direct food ingredient, and that the regulation for a specific indirect food use implied that caprylic acid is not GRAS for other indirect food uses.

The Commissioner agrees that this rule is intended to limit the indirect GRAS food use of caprylic acid to the specifically stated use in cheese wraps. This is the case primarily because its use for this purpose is the only historically known or reported indirect food

use of the substance. Although the Commissioner does not necessarily disagree with this comment's general comparative analysis of consumer exposure to food additives through direct and indirect food uses, new indirect food uses of caprylic acid may substantially increase consumer exposure beyond the 2,500-pound total annual poundage evaluated in connection with this regulation. Such potential uses cannot be determined to be safe without greater knowledge of potential human exposure. This rule is not intended, however, to exclude any future petitions for other indirect uses of caprylic acid.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner amends parts 172, 182, 184, and 186 as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

§ 172.515 [Amended]

1. In § 172.515 *Synthetic flavoring substances and adjuvants* by deleting the entry for "Octanoic acid; caprylic acid" from the list of substances in paragraph (b).

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§ 182.3025 [Deleted]

2. By deleting § 182.3025 *Caprylic acid*.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. By adding new § 184.1025 to read as follows:

§ 184.1025 *Caprylic acid*.

(a) Caprylic acid [$\text{CH}_3(\text{CH}_2)_6\text{COOH}$, CAS Reg. No. 124-07-2] is the chemical name for octanoic acid. It is considered to be a short or medium chain fatty acid. It occurs normally in various foods and is commercially prepared by oxidation of *n*-octanol or by fermentation and fractional distillation of the volatile fatty acids present in coconut oil.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).¹

¹Copies may be obtained from: National Academy of Sciences, 2101 Constitution Avenue NW., Washington, D.C. 20037.

(c) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(d) The ingredient is used in foods in accordance with § 184.1(b)(1), at levels not to exceed good manufacturing practice. Current good manufacturing practices result in maximum levels, as served, of: 0.013 percent for baked goods as defined in § 170.3(n)(1) of this chapter; 0.04 percent for cheeses as defined in § 170.3(n)(5) of this chapter; 0.005 percent for fats and oils as defined in § 170.3(n)(12) of this chapter, for frozen dairy desserts as defined in § 170.3(n)(20) of this chapter, for gelatins and puddings as defined in § 170.3(n)(22) of this chapter, for meat products as defined in § 170.3(n)(29) of this chapter, and for soft candy as defined in § 170.3(n)(38) of this chapter; 0.016 percent for snack foods as defined in § 170.3(n)(37) of this chapter; and 0.001 percent or less for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

4. By adding new § 186.1025 to read as follows:

§ 186.1025 *Caprylic acid*.

(a) Caprylic acid [$\text{CH}_3(\text{CH}_2)_6\text{COOH}$, CAS Reg. No. 124-07-2] is the chemical name for octanoic acid. It is considered to be a short or medium chain fatty acid. It occurs normally in various foods and is commercially prepared by oxidation of *n*-octanol or by fermentation and fractional distillation of the volatile fatty acids present in coconut oil.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).¹

(c) The ingredient is used as an antimicrobial (preservative) in cheese wraps as defined in § 170.3(o)(2) at levels not to exceed good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Effective date: This regulation is effective on June 8, 1978.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))).

Dated: April 28, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

NOTE.—Incorporation by reference was approved by the Director of the Office of the

Federal Register on July 10, 1973, and is on file at the Federal Register Library.

[FR Doc. 78-12390 Filed 5-8-78; 8:45 am]

[4110-03]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Lasalocid With Roxarsone

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a supplemental new animal drug application (NADA) filed by Hoffmann-La Roche, Inc., providing for the use of lasalocid in combination with roxarsone in complete chicken feeds, at a concentration of 68 to 113 grams of lasalocid per ton. This application also adds Hess and Clark as an additional sponsor for the roxarsone used in the combination and revises the labeling to delete the claim for the reduction of oocysts.

EFFECTIVE DATE: May 9, 1978.

FOR FURTHER INFORMATION CONTACT:

Adriano R. Gabuten, Bureau of Veterinary Medicine (HFV-149), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4913.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., Nutley, N.J. 07110, filed a supplemental NADA (102-485V) providing that use of lasalocid sodium in combination with roxarsone in the feed of broiler and fryer chickens be permitted in the range of 68 to 113 grams per ton (0.0075 to 0.0125 percent), that Hess and Clark, Division of Rhodia, Inc., Ashland, Ohio 44805, be an added sponsor of roxarsone for use in this combination, and that the labeling be revised to delete the claim for the reduction of oocysts due to *E. tenella*.

The provisions of this supplement will not result in expanded use of roxarsone. Accordingly, the underlying human safety data were not reevaluated. Therefore, approval of this supplement does not constitute reaffirmation of the underlying human safety data for use of roxarsone in broiler or fryer feed.

In accordance with the freedom of information regulations and § 514.11(e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of the safety and effectiveness data and information submitted to support approval of this application

is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFC-20), Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, Monday through Friday, 9 a.m. to 4 p.m.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Com-

missioner of Food and Drugs (21 CFR 5.1), part 558 is amended in § 558.311(e) by revising the second entry in the table to read as follows:

§ 558.311 Lasalocid sodium.

• • • • •
(e) Conditions of use. • • •

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(2) 68 (0.0075 pct) to 113 (0.0125 pct).	Roxarsone 45.4 (0.005 pct).	Broiler or fryer chickens; for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivatt</i> , and <i>E. maxima</i> and as an aid in the reduction of lesions due to <i>E. tenella</i> .	For broiler or fryer chickens only; feed continuously as the sole ration; as sole source of organic arsenic; withdraw 5 d before slaughter; roxarsone provided by Nos. 017210 and 011801 in sec. 510.600(c) of this chapter.	000004

Effective date: May 9, 1978.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: May 1, 1978.

C. D. VAN HOUWELING,
Director, Bureau of Veterinary Medicine.

[FR Doc. 78-12385 Filed 5-8-78; 8:45 am]

[4110-03]

SUBCHAPTER F—BIOLOGICS

[Docket No. 78N-0101]

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

Color Coding for Blood Grouping Serum; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: This rule corrects the biologics regulations to delete reference to the Standard Ink Book and provide that final container labels of blood grouping serum may be color coded with a visual match to a specific color sample designated by the Director, Bureau of Biologics. The Standard Ink Book, which was published by the Government Printing Office, is out of print, and the Commissioner of Food and Drugs is therefore approving, upon request, other coloring systems.

EFFECTIVE DATE: This document corrects regulations that become effective August 7, 1978.

ADDRESS: Written comments to the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Al Rothschild, Bureau of Biologics (HFB-620), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, Md. 20014, 301-443-1306.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of October 7, 1977 (42 FR 54534), the Commissioner of Food and Drugs published additional standards for the manufacture of blood grouping serum (21 CFR 660.20 through 660.29). Section 660.28(a)(1) of these standards requires that the final container label of all blood grouping sera be completely white, except that all or a portion of the final container label of certain specified antisera may be color coded with a visual match of the specific color samples identified in § 60.28(a)(1) and