Subpart—Pack Specification as to Size

* * * * *

§ 993.515 Size categories.

* * * * *

(b) *Nomenclature designations.* Each of the following is a nomenclature size category:

(1) Extra large;

(2) Large; and

(3) Medium

(c) *Nomenclature designations defined.* As used in paragraph (b) of this section:

(1) "Extra large" means any size count which falls within the range of 25 to 40 prunes, inclusive, per pound;

(2) Large" means any size count which falls within the range of 40 to 60 prunes, inclusive, per pound; and

(3) "Medium" means any size count which falls within the range of 60 to 85 prunes, inclusive, per pound.

* * * * *

§ 993.517 [Amended]

2. The last sentence of § 993.517 is amended by changing the number "36" to "25". As amended, that sentence reads, in part: "Prunes in any lot of which the maximum size count is less than 25 shall be clearly marked by the handler in terms of the applicable numerical designation prescribed in § 993.515(a);".

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated July 21, 1981, to become effective August 1, 1981, except that handlers may continue to pack consumer packages of prunes labeled Small, Breakfast, or Petite, as those terms are now defined in § 993.515(c)(4), until August 31, 1981.

D. S. Kuryloski,

Acting Director, Fruit and Vegetable Division.

[FR Doc. 81-21700 Filed 7-23-81; 8:45 am]

BILLING CODE 3410-02-M

Food Safety and Inspection Service

9 CFR Parts 312 and 316

[Docket No. 80-039F]

Official Marking Devices for Imported Products; Use of Hexagon-Shaped Brands for Imported Horsemeat and Other Equines

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This rule amends the Federal meat inspection regulations to require a hexagon-shaped brand to be used to apply the official import inspection legend on horsemeat and other equine meat and meat food products in order to identify the products as imported, inspected and passed. It also requires each official import inspection establishment to furnish the official marking devices used in its establishment rather than having them furnished by the Department.

EFFECTIVE DATE: July 21, 1981.

FOR FURTHER INFORMATION CONTACT: Dr. John C. Prucha, Director, Slaughter Inspection Standards and Procedures Division, Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 447–3219.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The Food Safety and Inspection Service (FSIS) has determined, in accordance with Executive Order 12291, that this final rule is not a "major rule". No significant costs or requirements are being imposed on the affected industry. The only cost impact on the affected industry would be the price of the marking devices that each official import inspection establishment would have to purchase. Consequently, the implementation of this rule should not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Background

On December 12, 1980, FSIS (previously Food Safety and Quality Service), published a proposed rule in the **Federal Register** (45 FR 81764) to amend the Federal meat inspection regulations (9 CFR Parts 312) and 316) to require (1) a hexagon-shaped official inspection legend to be used to identify all inspected and passed horse and other equine meat and meat food products, and (2) official import inspection establishments to furnish the import brands used in their establishments.

Part 312 of the Federal meat inspection regulations (9 CFR Part 312 currently requires a hexagon-shaped official inspection legend to be used at official establishments to identify federally inspected and passed carcasses, parts of carcasses and meat food products of horses, mules or other equines slaughtered in the United States. Part 312 also currently requires a circle-shaped inspection legend to be used to identify federally inspected and passed carcasses, parts of carcasses, and meat food products of other animal species, namely cattle, sheep, swine and goats slaughtered in the United States. However, § 312.7 of the federal meat inspection regulations (9 CFR 312.7) requires the circle-shaped inspection legend to be applied to inspected and passed imported meat and meat food products. Accordingly, a circle-shaped inspection legend currently is required to be applied to all federally inspected and passed carcasses, parts of carcasses and meat food products of cattle, sheep, swine and goats, and imported carcasses, parts of carcasses and meat food products of horses, mules or other equines; however, a hexagon-shaped inspection legend is required to be applied to domestic carcasses, parts of carcasses and meat food products of horses, mules, or other equines.

This rule amends § 312.7 to make it consistent with the other provisions of that part and requires a hexagon-shaped brand to be used to apply the official import inspection mark on inspected and passed horse or other equine meat and meat food products, regardless of whether the meat of meat food product is imported or domestic.

This rule also requires each official import inspection establishment to furnish the brands or any other device used to mark products at its establishment. This rule eliminates the current inconsistency in the regulations which requires only domestic official establishments to furnish the brands or marking devices used at their establishment.

As a result of the proposal, 23 comments were received from 14 individuals, 3 State meat inspection program officials, 1 foreign country, 2 beekeeper associations, 1 beekeeper, 1 beekeeper attorney, and the National Pork Producers' Council. Seventeen comments generally supported the proposal while 6 comments opposed the use of the hexagon brand. No comments were received on the proposal that official import inspection establishments furnish their import brands. The objecting comments raised two issues:

1. Four of the comments opposing the use of the hexagon-shaped brand were from persons associated with the

[1] Pursuant to the reorganizational plans outlined in USDA Secretary's Memo 1000-1, issued June 17, 1981, the Food Safety and Quality Service has become the Food Safety and Inspection Service. A notice detailing the Agency's reorganization is now being drafted for later publication.

beekeeping industry who claimed that this import brand may be confused with honey and other bee related products because the hexagon shape has long been associated with bees and beehives. The Wyoming Department of Agriculture similarly objected because the brand currently used to identify Wyoming inspected meat products is hexagonal. The Agency believes that since the hexagonal brand has been used on federally inspected domestic horsemeat for over 60 years and the word "horsemeat" or "equine-meat" appears inside the hexagon to clearly identify the product, there is no evidence that there actually will be confusion.

2. The Canadian Department of Agriculture expressed concern that the brand would be an additional requirement on the exporting country. This would not be the case since the brand is applied at the official import establishment in the United States to identify meat and meat food products that have been federally inspected and passed.

In consideration of the foregoing, the Federal meat inspection regulations (9 CFR Parts 312 and 316) are revised to read as follows:

1. The authority citation for Parts 312 and 316 reads as follows:

Authority: (34 Stat. 1264, 79 Stat. 903, as amended, 81 Stat. 584, 84 Stat. 91, 438, 21 U.S.C. 71 *et seq.*, 601 *et seq.*, 33 U.S.C. 466–466k).

2. Section 312.7(a), (b), and (d) (9 CFR 312.7(a), (b), and (d)) are revised to read as follows:

§ 312.7 Official import inspection marks and devices.

(a) When import inspections are performed in official import inspection establishments, the official inspection legend, as required by Part 327 of this subchapter, to be applied to imported meat and meat food products shall be in the approprite form [2] as herein specified.

[2] The number "I–38" is given as an example only. The establishment number of the official import inspection establishment where the imported product is inspected shall be used in lieu thereof.

For application to cattle, sheep, swine, and goat carcasses, primal parts, and cuts, not in containers.

For application to outside containers of meat and meat food products prepared from cattle, sheep, swine, and goats.

For application to horse carcasses, primal parts, and cuts, not in containers.

For application to outside containers of horsemeat food products.

For application to mule and other (nonhorse) equine carcasses, primal parts, and cuts, not in containers.

For application to outside containers of equine meat food products.

(b) When import inspections are performed in official establishments, the official inspection legend, as required by Part 327 of this subchapter, to be applied to imported meat and meat food products, shall be the appropriate form as specified in §§ 312.2 and 312.3 of this Part.

* * * * *

(d) Devices for applying "United States Refused Entry" marks shall be furnished to Program inspectors by the Department.

3. Section 316.4(a) (9 CFR 316.4(a)) is revised to read as follows:

§ 316.4 Marking devices; to be furnished by official establishments; control of.

(a) The operator of each official establishment or official import inspection establishment shall furnish such ink brands, burning brands, and any other device for marking products with official marks as the Administrator may determine is necessary for marking products at such establishment. The official inspection legend on such a device shall be as prescribed in Part 312 of this subchapter.

* * * * *

Done at Washington, D.C. on July 8, 1981.

Donald L. Houston,

Administrator, Food Safety and Inspection Service.

[FR Doc. 81-21656 Filed 7-23-81; 8:45 am]

BILLING CODE 3410-DM-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 81F-0081]

21 CFR Part 172

Food Additives Permitted for Direct Addition to Food for Human Consumption; Fish Protein Isolate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the food additive regulations to provide for the safe use of fish protein isolate as a food supplement. This action is being taken in response to a petition filed by Concentrados Marinos, S.A., Lima, Peru.

DATES: Effective July 24, 1981; objections by August 24, 1981.

ADDRESS: Written objections may be sent to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Garnett R. Higginbotham, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Notice was published in the **Federal Register** of April 3, 1981 (46 FR 20303) that a food additive petition (FAP 1A3538) had been filed on behalf of Concentrados Marinos, S.A., P.O. Box/Casilla 4441, Lima 100, Peru, proposing that Subpart D of Part 172 (21 CFR Part 172) of the food additive regulations be amended by adding a new section to provide for the safe use of fish protein isolate as a food supplement.

Having evaluated data in the petition and other relevant material, FDA concludes that the proposed food additive use is safe and that Part 172 should be amended as set forth below.

The agency has considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's findings of no significant impact and its environmental assessment may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Subpart D of Part 172 is amended by adding new § 172.340, to read as follows:

§ 172.340 Fish protein isolate.

(a) The food additive fish protein isolate may be safely used as a food supplement in accordance with the following prescribed conditions:

(1) The additive shall consist principally of dried fish protein prepared from the edible portions of fish after removal of the heads, fins, tails, bones, scales, viscera, and intestinal contents.

(2) The additive shall be derived only from species of bony fish that are generally recognized by qualified scientists as safe for human consumption and that can be processed as prescribed to meet the required specifications.

(3) Only wholesome fresh fish otherwise suitable for human consumption may be used. The fish shall be handled expeditiously under sanitary conditions. These conditions shall be in accordance with recognized good manufacturing practice for fish to be used as human food.

(4) The additive shall be prepared by extraction with hexane and food-grade ethanol to remove fat and moisture. Solvent residues shall be reduced by drying.

(b) The food additive meets the following specifications: (Where methods of determination are specified, they are Association of Official Analytical Chemists Methods, 13th ed., 1980, which are incorporated by reference).[1]

(1) Protein content , as N X 6.25, shall not be less than 90 percent by weight of the final product, as determined by the method described in section 2.057, Improved Kjeldahl Method for Nitrate-Free Samples (20)—Official Final Action.

(2) Moisture content shall not be more than 10 percent by weight of the final product, as determined by the method described in section 24.003, Air Drying (1)—Official First Action.

(3) Fat content shall not be more than 0.5 percent by weight of the final product, as determined by the method described in section 24.005, Crude Fat or Ether Extract—Official Final Action.

(4) Solvent residues in the final product shall not be more than 5 parts per million of hexane and 3.5 percent ethanol by weight.

(5) The viable microbial content of the final product shall be:

(i) Less than 10,000 organisms/gram by aerobic plate count.

(ii) Less than 10 yeasts and molds/gram.

(iii) Negative for *Salmonella, E. coli,* coagulase positive *Staphylococci, Clostridium perfringens, Colstridium botulinum,* or any other recognized microbial pathogen or any harmful microbial toxin.

Any person who will be adversely affected by the foregoing regulation may at any time on or before August 24, 1981 submit to the Dockets Management Branch (address above), 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

[1] Copies are available from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or examined at the Office of the Federal Register, 1100 L St. NW, Washington, DC 20408.

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 docket number found in brackets in the heading of this regulation. Received objections may be seen in in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective July 24, 1981.

(Secs. 201(s) 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348))

Dated: July 10, 1981.

Note.—Incorporation by reference provisions approved by the Director, Office of the Federal Register on July 17, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-21328 Filed 7-17-81; 11:53 am]

BILLING CODE 4110-03-M

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21 CFR Parts 700, 710, 720, and 730

[Docket No. 80N-0346]

Modification in Voluntary Registration of Cosmetic Industry Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reducing the reporting burden of the persons voluntarily participating in the registration of cosmetic product establishments and the filing of cosmetic product formulations, raw material compositions, and consumer adverse reactions. The reduction will have no significant effect on the quality of the cosmetics registration programs.

EFFECTIVE DATE: This rule becomes effective August 24, 1981.

FOR FURTHER INFORMATION CONTACT: Earl L. Richardson, Bureau of Foods (HFF-444), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1094.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 7, 1980 (45 FR 73960), FDA proposed to reduce the reporting burden of the persons participating in the voluntary cosmetics registration program by eliminating certain items of information. The voluntary registration program provides for the registration of cosmetic product establishments (21 CFR Part 710), filing of cosmetic product ingredient and cosmetic raw material composition statements (21 CFR Part 720), and filing of cosmetic product experiences (21 CFR Part 730). A review of the reporting requirements and impact of the reported information on the quality of the voluntary registration and filing programs had demonstrated that these items could be eliminated without significantly affecting the respective data files. It was also expected that exclusion of these items would motivate other cosmetic product manufacturers and distributors to beome participants. Interested persons were given until January 6, 1981, to submit written comments about the proposed elimination of the specified data elements.

One comment was received during the comment period in support of the proposed regulation. The comment, from a cosmetic trade association, fully supported the proposed modification in the voluntary registration of cosmetic industry data. It agreed that the proposed reduction would facilitate registration without diminishing the quality of the voluntary registration program and that the changes might encourage other companies to participate in the program.

The regulation will become effective as proposed. Revised forms FD-2511, FD-2512, FD-2513, FD-2514, and FD-2704 are available from FDA. The regulation does not require resubmission of previously registered data.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 301, 601, 602, 701(a), 52 Stat. 1042–1043 as amended, 1054 as amended, 1055 (21 U.S.C. 321(n), 331, 361, 362, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Title 21 of the Code of Federal Regulations is amended as follows:

PART 700—GENERAL

§ 700.3 [Amended]

1. In § 700.3 *Definitions,* by removing paragraph (r).

PART 710—VOLUNTARY REGISTRATION OF COSMETIC PRODUCT ESTABLISHMENT

§ 710.4 [Amended]

2. In § 710.4 *Information requested,* by removing the phrase "the kind of ownership or operation (e.g., individually owned, partnership, or corporation)" and by revising the parenthetical words "(manufacturer, packer, and/or distributor)" to read "(manufacturer and/or packer)."

PART 720—VOLUNTARY FILING OF COSMETIC PRODUCT INGREDIENT AND COSMETIC RAW MATERIAL COMPOSITION STATEMENTS

§ 720.4 [Amended]

3. In § 720.4 *Information requested about cosmetic products,* by removing the second sentence of paragraph (d)(2) and footnotes (1) through (4) and by adding in the third sentence the parenthetical abbreviation "(CRMCS)" between the words "statement" and "number."

§ 720.5 [Amended]

4. In § 720.5 *Information requested about cosmetic raw materials,* by removing the third sentence of paragraph (c)(1) and footnotes (1) through (4) and by adding in the fourth sentence the parenthetical abbreviation "(CRMCS)" between the words "statement" and "number."

PART 730—VOLUNTARY FILING OF COSMETIC PRODUCT EXPERIENCES

§ 730.1 [Amended]

5. In § 730.1 *Who should file,* by removing the phrases "or a Form FD-2705 (Cosmetic Product Unusual Experience Report)," "and unusual reportable experiences," and "or unusual reportable experience."

§ 730.2 [Amended]

6. In § 730.2 *Time for filing,* by removing paragraph (b).

§ 730.3 [Amended]

7. In § 730.3 *How and where to file,* by removing the phrase "Form FD-2705 (Cosmetic Product Unusual Experience Report)" and the comma preceding it; by changing the name "Industry Guidance Branch" to read "Industry Programs Branch" and by removing the last sentence.

8. In § 730.4 by revising paragraph (a)(5) and by removing paragraphs (a)(7) and (8) and (b); by removing paragraph (c)(5); by removing in the introductory text of paragraph (d) the phrase "Form FD-2705 (Cosmetic Product Unusual Experience Report)" and the commas preceding and following it; by removing in paragraph (d)(1) and (3) the reference "(b)" and the commas preceding and following it; and by changing in paragraph (e) the reference "paragraphs (a) and (b)" to read "paragraph (a)."