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]

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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)."

§ 730.4 Information requested.

(a) * * *

(5) Total number of reportable experiences during this reporting period and number of these experiences requiring professional medical attention.

* * * * *

(7)–(8) [Reserved]

* * * * *

(b) [Reserved]

* * * * *

§ 730.7 [Amended]

9. In § 730.7 *Confidentiality of reports,* by removing "2705."

In accordance with Executive Order 12291, FDA has determined that this final rule does not constitute a "major rule" as defined by that order. The effect of this final rule is to lessen the economic costs so that more members of the cosmetic industry will participate in the voluntary registration of cosmetic industry data.

Effective date. The modification in voluntary registration of cosmetic industry data becomes effective on August 24, 1981.

(Secs. 201(n), 301, 601, 602, 701(a), 52 Stat. 1041–1043 as amended, 1054 as amended, 1055 (21 U.S.C. 321(n), 331, 361, 362, 371(a)))

Dated: July 8, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 115

Payment of Sioux Benefits; Eligibility Criteria and Application Procedures Governing Benefits

Correction

In FR Doc. 81–20511, appearing at page 36135 in the issue of Tuesday, July 14, 1981, the ninth line of § 115.5(c) on page 36137, column two, should have read, "administrative appeal procedures of 43 CFR".

BILLING CODE 1505-01-M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H–004M]

Occupational Exposure to Lead, New Trigger Levels for Medical Removal Protection; Denial of Petitions for Stays; Notice of Variance Applications; Interim Orders

Note.—This document originally appeared in the **Federal Register** for Thursday, July 23, 1981. It is reprinted in this issue to meet requirements for publication on the Tuesday/Friday schedule assigned to the Department of Labor.

AGENCY: Occupational Safety and Health Administration, Labor.

ACTIONS: Denial of petitions and notice of variance applications and interim orders.

SUMMARY: OSHA hereby denies petitions by the primary and secondary lead smelting industries for one-year, industry-wide stays of the new trigger levels for medical removal protection (MRP) under the lead standard (29 CFR 1910.1025(k)). The new triggers thus will take effect for lead smelters on July 21, 1981. OSHA also hereby denies the lead battery manufacturers' petition for reconsideration of OSHA's earlier denial of its request for an industry-wide stay. These actions are taken because data submitted by industry were insufficient to justify granting industry-wide stays.

The data did, however, show serious and potentially serious problems of compliance with the new triggers in certain smelting and battery manufacturing plants. As a result, conditioned upon OSHA receiving by August 3, 1981, for each such plant a variance application, certification of notice to affected employees, and written acceptance of the requirements of the Order, the Agency is granting interim orders under section 6(b)(6)(A) of the OSHA Act to those lead smelting and battery manufacturing plants that have supplied data sufficient to establish the need for relief. The interim orders relieve those facilities from having to comply with the 60/40 removal return triggers, but obligate them to comply with the 70/50 triggers, all other provisions of the lead standard, and certain other requirements set out in the Interim Order. OSHA also invites other eligible lead smelting and battery manufacturing plants, including those that have submitted data but have not been granted an Interim Order via this notice, if they choose, to apply individually for temporary variances. Finally, OSHA requests every applicant to submit particular data needed by the Agency to determine whether to issue a temporary variance, and invites public comment on the variance requests.

DATES: The effective date of the new trigger levels (29 CFR 1910.1025(k) originally published on November 14, 1978 at 43 FR 53007) for primary and secondary smelters is July 21, 1981.

For all companies conditionally granted interim orders, variance applications, written acceptances and certifications must be received by August 3, 1981. All data requested herein by OSHA in support of each application for a temporary variance must be received by September 1, 1981. The last date for interested persons to submit comments on the variance applications is September 30, 1981. The last date for affected employers and employees to request a hearing on the applications is September 30, 1981.

ADDRESSES: Send applications, submissions, comments or requests for a hearing to: Office of Variance Determination, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3662, Third Street and Constitution Avenue, NW., Washington, D.C. 20210.

FOR FURTHER INFORMATION CONTACT: Mr. James J. Concannon, Director, Office of Variance Determination, at the above address, telephone: (202) 523–7144.

SUPPLEMENTARY INFORMATION:

A. Background

On March 3, 1981, OSHA published a notice in the **Federal Register** (46 FR 14897) delaying the effective date of the new removal and return trigger levels for medical removal protection (MRP) from March 1, 1981, as specified in the standard on occupational exposure to lead (29 CFR 1910.1025(k), November 14, 1978, 43 FR 53007) to April 1, 1981. That notice summarized the provisions of MRP and explained the need in the standard for progressively phased-in blood-lead levels triggering employee removal from, and subsequent return to, lead-exposed jobs. The notice also explained that the delay was granted as an interim measure in response to applications from certain employers and industry groups representing several lead industries for a one-year delay in the effective date of the new trigger levels. In the notice, interested persons were invited to submit information and views on all issues involved in the applications.

In support of their request for a stay of the 60 μg/100g removal and 40 μg/100g return triggers, the lead industries allege