

they were developed. To date, however, work on the specifications is still incomplete. Until the specifications are developed, peptones for direct food uses must comply with the description in § 184.1553 and be of food grade purity (21 CFR 182.1(b)(3) and 170.30(h)(1)).

The agency has previously determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. FDA has not received any new information or comments that would alter its previous determination.

In accordance with the Regulatory Flexibility Act, the agency has previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, the agency has previously considered the potential effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by that Order. FDA has not received any new information or comments that would alter its previous determination.

The agency's finding of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

List of Subjects in 21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients.

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 the Commissioner of Food and Drugs (21 CFR 5.10), Part 184 is amended by adding new § 184.1553, to read as follows:

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

§ 184.1553 Peptones.

(a) Peptones (CAS Reg. No. 977027-88-5) are a variable mixture of polypeptides, oligopeptides, and amino

acids that are produced by partial hydrolysis of casein, animal tissue, soy protein isolate, gelatin, defatted fatty tissue, egg albumin, or lactalbumin (whey protein). Peptones are produced from these proteins using proteolytic enzymes that either are considered to be generally recognized as safe (GRAS) or are regulated as food additives. Peptones are also produced by denaturing any of the proteins listed in this paragraph with safe and suitable acids or heat.

(b) FDA is developing food-grade specifications for peptones in cooperation with the National Academy of Sciences. In the interim, these ingredients must be of a purity suitable for their intended use.

(c) In accordance with § 184.1(b)(1), these ingredients are used in food with no limitation other than current good manufacturing practice. The affirmation of these ingredients as GRAS as direct human food ingredients is based upon the following current good manufacturing practice conditions of use:

(1) These ingredients are used as nutrient supplements as defined in § 170.3(o)(20) of this chapter; as processing aids as defined in § 170.3(o)(24) of this chapter; and as surface-active agents as defined in § 170.3(o)(29) of this chapter.

(2) These ingredients are used in food at levels not to exceed current good manufacturing practice.

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

Effective date. This regulation shall be effective July 23, 1984.

(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: May 23, 1984.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 84-16510 Filed 6-20-84; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 680

[Docket No. 80N-0051]

Allergenic Products; Criteria for Source Materials

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations to establish manufacturing or propagation criteria

for certain allergenic source materials (molds, and mammals and birds), require the submission of a listing of allergenic source materials and suppliers by licensed manufacturers, and require records of the manufacturing process of each lot of source material. This regulation is intended to give manufacturers of the final products and FDA increased assurance that an allergenic source material has been properly obtained, identified, or processed and is safe for use in an injectable human drug product.

DATE: Effective October 19, 1984.

FOR FURTHER INFORMATION CONTACT: Michael L. Hooton, Center for Drugs and Biologics (formerly National Center for Drugs and Biologics) (HFN-368), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1306.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 15, 1983 (48 FR 32361), FDA republished regulations for allergenic source materials that were first proposed on September 26, 1978 (43 FR 43472).

Allergenic Products, defined in 21 CFR 680.1(a), include any licensed biological product intended for the diagnosis, prevention, or treatment of allergies. Allergenic source materials used to produce an Allergenic Product include allergens, such as molds, feathers, and hair. It is essential that the source material be suitable for manufacture into final Allergenic Products, most of which are administered to humans by injection. FDA's Center for Drugs and Biologics has examined certain allergenic source materials that unlicensed suppliers were shipping to licensed manufacturers of Allergenic Products. FDA's examinations revealed that occasionally the unlicensed source material suppliers ship such manufacturers incorrectly identified or contaminated allergenic source materials. If licensed manufacturers use incorrectly identified or contaminated source materials, the resulting licensed Allergenic Product used by practitioners may be harmful. If a patient receives and reacts to an incorrectly identified diagnostic Allergenic Product, the practitioner may give a patient a long series of costly and ineffective injection treatments for the wrong allergen. If a practitioner gives a patient an Allergenic Product that is contaminated with an unknown allergen, the patient may become sensitized to the contaminant(s), unnecessarily complicating the patient's treatment and causing a worsening of the patient's condition. Also, the unknown

contaminating allergen rarely may cause a severe allergic reaction in a patient.

The criteria established in this final rule for manufacture or propagation of a specific source material provide requirements to assure the identity and purity of molds or the good health of certain animals (mammals and birds) intended for use as an allergenic source material. However, the requirements in this final rule concerning listing of nonlicensed establishments and recordkeeping apply to any licensed manufacturer who uses any allergenic source material to manufacture a final Allergenic Product. Notwithstanding the requirements in this final rule that apply to nonlicensed source material establishments, FDA emphasizes that the manufacturer of the licensed final product must continue to ensure that the allergenic source materials used in its manufacturing will produce a final product that meets current standards of purity and quality.

Interested persons were provided 60 days to submit comments on the proposal of July 15, 1983. FDA received three letters of comment in response to the proposals and several letters included more than one comment. A summary of the comments received and FDA's responses follow.

1. One comment on proposed § 680.1(b)(2)(iii) concerning the requirements for processing molds requested that the requirement be clarified to specify that only three consecutive lots representative of the processing of molds need to be tested and test data approved by FDA, not three consecutive lots of each species of molds that are produced.

FDA agrees with the comment. Manufacturers may use one standard operating procedure for processing several species of molds, if the procedure is applicable to each such species. If different procedures are necessary for the processing of a certain species of mold, a separate standard operating procedure for that species of mold, including tests on three consecutive lots of mold, is required. Accordingly, in the final rule § 680.1(b)(2)(iii) is amended to clarify that only three consecutive lots of a representative species of mold produced by a particular standard operating procedure are required to be tested to determine the acceptable limits and kinds of contamination in the molds.

2. One comment on proposed § 680.1(b)(2)(iii) concerning the requirements for standard operating procedures for molds stated that manufacturers of allergenic extracts already are required to have written standard operating procedures approved

by FDA and, therefore, the proposed requirements under § 680.1(b)(2)(iii) are unnecessary.

FDA disagrees with the comment. Although §§ 211.100, 211.160, 211.180, 601.2, and 601.12 of the regulations now require licensed manufacturers of Allergenic Products to maintain written standard operating procedures that have been approved by FDA, these regulations do not prescribe specific requirements for the processing of molds. FDA intended that proposed § 680.1(b)(2)(iii) clarify the requirements concerning the standard operating procedures for the processing of molds. Further, proposed § 680.1(b)(2)(iii) applies to molds produced at an unlicensed establishment and intended for use as an allergenic source material by a manufacturer of a licensed final Allergenic Product. In such cases, the licensed manufacturer may prepare, and submit to FDA for approval, the standard operating procedures of the unlicensed manufacturer. Alternatively, an unlicensed mold manufacturer may prepare, and submit to FDA for approval, its own standard operating procedure in the form of a master file (see 21 CFR 314.11).

3. Three comments on proposed § 680.1(b)(3)(ii) concerning the requirement for quarantine of animals and use of only healthy animals acknowledged the need for use only of animals that are in good health and free from detectable skin diseases as a source material for Allergenic Products. However, two comments said that a quarantine period prior to collection of the allergen is not necessary, that it may increase costs, and that the same objective would be achieved by requiring a veterinarian or other competent individual to inspect and certify the good health of the animal.

FDA agrees with the comments. Based on the information provided to FDA by the comments, FDA now believes that a quarantine period is not required if prior to collection of the allergen the good health of the animals is determined by a licensed veterinarian or a competent individual under the supervision and instruction of a licensed veterinarian. The manufacturer's standard operating procedures must specify a reasonable time limit between the veterinary examination and collection of the allergen, and the manufacturing records must state clearly how the good health of the animals has been determined. Because FDA and the comments agree that only healthy animals should be used for allergenic source materials, the agency will continue to review this issue and, if further requirements are determined to be necessary, will amend

the regulations appropriately. Accordingly, in the final rule § 680.1(b)(3)(ii) is amended to provide for a determination of good health of animals and delete the requirement for animal quarantine.

4. One comment on proposed § 680.1(b)(3)(ii) concerning the requirement for veterinary care of animals said that veterinary certification or supervision is unnecessary for an animal used as a source of allergens when these allergens are obtained from a professional pet groomer. The comment asked that FDA clarify the veterinary care requirements related to a source material such as feathers collected from animals obtained from dealers licensed by the U.S. Department of Agriculture (USDA) and processed feathers collected from feather-stuffed materials.

FDA disagrees with the comment. FDA disagrees that the veterinary examination that would be required under § 680.1(b)(3)(ii) is unnecessary where the source material of animal origin is obtained from an animal pet tended by a professional pet groomer. Because FDA is eliminating in the final rule the requirement for animal quarantine (see paragraph 3 above), the requirement for veterinary examination of animals, including pets, is of added importance to assure that the allergenic source material is derived from healthy animals.

Therefore, allergenic source material collected from an animal that is a pet may be used in the manufacture of an Allergenic Product, if the veterinary examination of the animal is performed within the timeframe specified in the manufacturer's standard operating procedure that has been approved by FDA and the manufacturer can be certain that its labeling of the final product accurately identifies the source material used in the manufacture of that final product. Further, the regulation allows use of other allergenic source materials of epidermal origin, such as bird feathers that are obtained from dealers licensed by USDA and bird feathers used to produce a feather-stuffed material, when a veterinary examination of the animal is performed within the timeframe specified in the manufacturer's standard operating procedure. The veterinary examination may be performed at a location other than the licensed manufacturer of the Allergenic Product, including the location of a licensed dealer, if the manufacturing records identify the veterinary examiner and the time and location of the examination. FDA proposed that animals obtained from

dealers licensed by USDA be exempt from the specific quarantine and veterinary care requirements because USDA's provisions for licensed dealers prohibit the housing of animals of different species in the same primary enclosure and require that the establishment of appropriate programs of veterinary care are at least as stringent as the requirements proposed by FDA. FDA's proposed regulation was not intended to establish different criteria for animals obtained from such licensed dealers and animals obtained from other sources. Because FDA's regulation neither prohibits the use of allergenic source material from animals obtained from such licensed dealers nor imposes any additional requirements for use of such animals, FDA believes that the reference to licensed dealers in the proposed codified text is unnecessary and that the regulation would be clarified by deleting that reference. Accordingly, in the final rule FDA is amending § 680.1(b)(3)(vi) by deleting the reference to licensed dealers.

5. One comment on proposed § 680.1(c) concerning the required listing of source materials and suppliers stated that such listing information should be treated by FDA as confidential business information.

FDA agrees that under the applicable provisions of the Freedom of Information Act (5 U.S.C. 552(b)) and FDA regulations concerning confidential information (21 CFR 20.61 and 601.51), the listing required from each licensed manufacturer of Allergenic Products under § 680.1(c) will not be available for public disclosure.

6. One comment asked that the final rule permit a manufacturer to process further a source material that did not comply with the manufacturer's own specifications. Such processing may include cleaning and defatting in preparation for proper storage.

FDA advises that this rule will not prohibit further processing of a source material that does not comply with a manufacturer's own specifications. There are approximately 2,000 different source materials used to make Allergenic Products. It may be appropriate to perform further processing steps on some of those source materials and such processing steps and specific source materials should be identified in the manufacturer's standard operating procedures. When a manufacturer follows the applicable regulations and its FDA-approved standard operating procedures, further processing of a source material to enable the source material to meet the manufacturer's specifications is permitted.

FDA proposed that this rule be effective 60 days after its date of publication in the **Federal Register**. No comments were received concerning the effective date. However, FDA now believes that an effective date of 60 days after publication of the final rule may not allow sufficient time for manufacturers to prepare to implement the rule. FDA believes that an effective date of 120 days after publication would be appropriate and would eliminate any potential hardship on manufacturers in meeting the requirements of this rule. Therefore, this regulation is effective on October 19, 1984. In addition to the other changes discussed above that have been made in the final rule, the references to the Director, Office of Biologics, are changed to the Director, Office of Biologics Research and Review (HFN-800), Center for Drugs and Biologics, to reflect a recent reorganization within FDA (March 19, 1984; 49 FR 10168).

The agency has determined pursuant to 21 CFR 25.25(b)(10) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Section 680.1(c) of this rule contains new collection of information requirements. As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA submitted a copy of the proposal for this rule to the Office of Management and Budget (OMB) for its review of these collection of information requirements. OMB has approved these requirements and has assigned to them OMB control number 0910-0161.

FDA has reexamined the regulatory impact and regulatory flexibility implications of the regulations in accordance with Executive Order 12291 and the Regulatory Flexibility Act. The agency concludes that 18 Allergenic Product manufacturers will be affected by these requirements, of which approximately 14 are small manufacturers. Costs per firm could possibly vary from zero to several thousand dollars, depending upon current practices, number of source suppliers, kinds of source materials, and applicability of exemptions. The anticipated costs are insufficient to warrant designation of this rule as a major rule under any of the criteria specified under section 1(b) of Executive Order 12291 or to require a regulatory flexibility analysis. Accordingly, under section 605(b) of the Regulatory Flexibility Act, the Commissioner of Food and Drugs certifies that this

rulemaking will not have a significant economic impact on a substantial number of small entities. A copy of the threshold assessment supporting this determination is on file with the Dockets Management Branch.

List of Subjects in 21 CFR Part 680

Biologics, Blood.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 501, 510, 704, 52 Stat. 1049-1050 as amended, 67 Stat. 477 as amended, 76 Stat. 794-795 as amended (21 U.S.C. 351, 360, 374)) and under the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)) and under 21 CFR 5.11, Part 680 is amended as follows:

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

1. In § 680.1 by revising paragraph (b) and adding new paragraphs (c) and (d) to read as follows:

§ 680.1 Allergenic products.

(b) *Source materials*—(1) *Criteria for source material*. Only specifically identified allergenic source materials that contain no more than a total of 1.0 percent of detectable foreign materials shall be used in the manufacture of Allergenic Products, except that this requirement shall not apply to molds and animals described under paragraph (b)(2) and (3) of this section, respectively. Source materials such as pelts, feathers, hairs, and danders shall be collected in a manner that will minimize contamination of the source material.

(2) *Molds*. (i) Molds (excluding rusts and smuts) used as source material in the manufacture of Allergenic Products shall meet the requirements of § 610.18 of this chapter and § 680.2 (a) and (b).

(ii) Mold cultures shall be free of contaminating materials (including microorganisms) prior to harvest, and care shall be taken to minimize contamination during harvest and subsequent processing.

(iii) Mold manufacturers shall maintain written standard operating procedures, developed by a qualified individual, that will ensure the identity of the seed culture, prescribe adequate processing of the mold, and specify the acceptable limits and kinds of contamination. These limits shall be based on results of appropriate tests performed by the manufacturer on at least three consecutive lots of a mold that is a representative species of mold subject to the standard operating procedures. The tests shall be performed at each manufacturing step during and

subsequent to harvest, as specified in the standard operating procedures. Before use of the mold as a source material for Allergenic Products, in accordance with 21 CFR 601.2, the standard operating procedures and test data from the three representative lots described above shall be submitted to and approved by the Director, Office of Biologics Research and Review (HFN-800), Center for Drugs and Biologics.

(Collection of information requirements approved by the Office of Management and Budget and assigned OMB control number 0910-0124.)

(3) *Mammals and birds*—(i) *Care of animals*. Animals intended as a source material for Allergenic Products shall be maintained by competent personnel in facilities or designated areas that will ensure adequate care. Competent veterinary care shall be provided as needed.

(ii) *Health of animals*. Only animals in good health and free from detectable skin diseases shall be used as a source material for Allergenic Products. The determination of good health prior to collection of the source material shall be made by a licensed veterinarian or a competent individual under the supervision and instruction of a licensed veterinarian provided that the licensed veterinarian certifies in writing that the individual is capable of determining the good health of the animals.

(iii) *Immunization against tetanus*. Animals of the equine genus intended as a source material for Allergenic Products shall be treated to maintain immunity to tetanus.

(iv) *Reporting of certain diseases*. In cases of actual or suspected infection with foot and mouth disease, glanders, tetanus, anthrax, gas gangrene, equine infectious anemia, equine encephalomyelitis, or any of the pock diseases among animals intended for use or used as source material in the manufacture of allergenic Products, the manufacturer shall immediately notify the Director, Office of Biologics Research and Review (HFN-800), National Center for Drugs and Biologics.

(v) *Dead animals*. Dead animals may be used as source material in the manufacture of Allergenic Products: *Provided*, That (a) the carcasses shall be frozen or kept cold until the allergen can be collected, or shall be stored under other acceptable conditions so that the postmortal decomposition processes do not adversely affect the allergen, and (b) when alive, the animal met the applicable requirements prescribed in paragraph (b)(3) (i), (ii), and (iii) of this section.

(vi) *Mammals and birds inspected by the U.S. Department of Agriculture*. Mammals and birds, subject to inspection by the U.S. Department of Agriculture at the time of slaughter and found suitable as food, may be used as a source material, and the requirements of paragraph (b)(3) (i) through (iv) of this section do not apply in such a case. Notwithstanding U.S. Department of Agriculture inspection, the carcasses of such inspected animals shall be frozen or kept cold until the allergen is collected, or shall be stored under other acceptable conditions so that the postmortal decomposition processes do not adversely affect the allergen.

(c) *Listing of source materials and suppliers*. Each licensed manufacturer shall initially list with the Director, Office of Biologics Research and Review (HFN-800), Center for Drugs and Biologics, the name and address of each of the manufacturer's source material suppliers. The listing shall identify each source material obtained from each source material supplier. The licensed manufacturers shall update the listing annually to include new source material suppliers or to delete those no longer supplying source materials. (Collection of information requirements were approved by the Office of Management and Budget and assigned OMB control number 0910-0161.)

(d) *Exemptions*. (1) Exemptions or modifications from the requirements under paragraph (b) of this section shall be made only upon written approval by the Director, Office of Biologics Research and Review (HFN-800), Center for Drugs and Biologics.

(2) Nonlicensed source material suppliers are exempt from drug registration.

2. In § 680.2 by reserving paragraph (e) and by adding new paragraph (f) to read as follows:

§ 680.2 Manufacture of allergenic products.

• • • • •

(e) [Reserved]

(f) *Records*. A record of the history of the manufacture or propagation of each lot of source material intended for manufacture of final Allergenic Products shall be available at the establishment of the manufacturer of the source material, as required by § 211.188 (OMB control number 0910-0139) of this chapter. A summary of the history of the manufacture or propagation of the source material shall be available at the establishment of the manufacturer of the final product.

Effective date. This regulation is effective on October 19, 1984.

(Secs. 501, 510, 704, 52 Stat. 1049-1050 as amended, 67 Stat. 477 as amended, 76 Stat. 794-795 as amended (21 U.S.C. 351, 360, 374)); (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262))

Mark Novitch,

Acting Commissioner of Food and Drugs.

Dated: June 5, 1984.

Margaret M. Heckler,

Secretary of Health and Human Services.

[FR Doc. 84-16506 Filed 6-20-84; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 140

Licensed Indian Traders and Bureau of Indian Affairs Employees Contracting and Trading With Indians

AGENCY: Bureau of Indian Affairs, Department of the Interior.

ACTION: Final rule.

SUMMARY: The Bureau of Indian Affairs is publishing this final rule which permits certain contracting and trading between employees of the Bureau of Indian Affairs and Indians. Certain types of trading are being regulated to prevent overreaching and possible conflicts of interest.

EFFECTIVE DATE: July 23, 1984.

SUPPLEMENTARY INFORMATION: This rule is being promulgated to implement Pub. L. 96-277 (94 Stat. 544; 18 U.S.C. 437) which repealed certain previous laws (25 U.S.C. 68, 68a, 87a and 441) dating back to the Indian Intercourse Act of 1834 (4 Stat. 38; 25 U.S.C. 68) which regulated trading between Federal employees and Indians. This final rule is published in exercise of the rulemaking authority delegated by the President to the Secretary of the Interior, pursuant to Executive Order No. 12328. Executive Order No. 12328 gives the Secretary of the Interior and the Secretary of Health and Human Services, respectively, the authority to regulate trade between employees of the Bureau of Indian Affairs (BIA) and the Indian Health Service (IHS) and Indians.

This final rule is being published in exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.

The Bureau of Indian Affairs published a proposed rule on October 7, 1983 (48 FR 45789), that offered the public an opportunity to comment on regulations which prescribed the conditions governing trade between employees of the Bureau of Indian

Affairs and Indians. Comments on the proposed rule were received from four sources—individuals, Indian organizations, law firms representing various Indian interests and BIA field officials.

The views expressed by commenters ranged from suggestions that the rule be more stringent than proposed, or, in the alternative, that the effort to regulate trading with Indians be abandoned. Representatives for several Indian interests stated that the provisions of the statute and the proposed rule do not go far enough to prevent BIA employees from overreaching their authority in their relationship with Indians.

The law requires that certain types of trading be regulated to prevent overreaching and possible conflicts of interest on the part of the BIA employee, when trading with Indians.

One commenter suggested that the regulations include employees of the Indian Health Service of the United States Department of Health and Human Services. The BIA has no jurisdiction over IHS employees. Regulations controlling IHS employees trading with Indians must be developed and issued by that Agency.

The following paragraphs summarize the comments and suggestions received and actions taken.

One commenter expressed disappointment that the proposed regulations do not resolve the issue presented in *Wright v. Schweiker, et al.*, No. 82-1392 (8th Cir. 1982), a suit brought by Indian employees of the Bureau of Indian Affairs and the Indian Health Service to obtain grazing permits from their tribes at a tribal rate—a rate which is less than the appraised values set by the Bureau of Indian Affairs for non-tribal members. Under previous law relating to employees trading with Indians, the BIA concluded the employees could not receive the preferential permits. Except as provided in Subsection (b)(2) Section 437 of Title 18, United States Code, Section 437 states that nothing shall be construed as preventing any employee of the Bureau who is Indian, of whatever degree of Indian blood, from obtaining or receiving any benefit or benefits made available to Indians generally or to any member of his or her particular tribe, under any Act of Congress, nor to prevent any such employee who is an Indian from being a member of or receiving benefits by reason of his or her membership in any Indian tribe, corporation, or cooperative association organized by Indians, when authorized under such rules and regulations as the Secretary of the Interior or his/her

designee has prescribed or shall prescribe.

Thus, grazing permits, such as those at issue in *Wright v. Schweiker*, for members of an Indian tribe, who are also employees of the BIA, are permissible trading transactions if not prohibited by 18 U.S.C. § 437(b)(2). Because the proposed rule did not define commercial trading, which is prohibited under § 437(b)(2), a definition of "commercial trading" has been added to the regulations at § 140.5(a)(7).

Several commenters asked what the term "fair market value" in Section 140.5(e)(2)(iii) means as applied to acquisition of grazing permits. When a grazing permit is issued to a tribal member it may be issued at a tribal rate which is less than the "fair market value" of the permit. Therefore, the following has been added to § 140.5(e)(2)(iii): "or the employee is the recipient of a benefit for tribal members for which a uniform charge to all members is made."

One commenter suggested that the last three words of the definition of "contract" in § 140.5(a)(5) be deleted since, presumably, transactions would involve sales both to and from Indians. The last three words have been deleted as suggested.

One commenter suggested that "any service" be deleted from § 140.5(d)(1) because BIA employees should not be providing services to Indians. This suggestion was rejected as the language is quoted directly from 18 U.S.C. § 437.

Several comments were received suggesting the exemption of transactions of less than \$1,000 was too low and several suggested \$1,000 was too high. The comments illustrate the difficulty of setting an appropriate level at which trading transactions will be approved and below which they will be exempt from approval. It was decided that the \$1,000 level would be retained for the present.

A comment that sales should be recorded to discourage attempts to evade the approval level by breaking up \$1,000 or more sales into smaller sales was rejected on the basis that its perceived effectiveness would not be worth the costs it would entail.

One commenter suggested that motor vehicle sales leave a great deal of room for overreaching and should not be exempt from approval. This suggestion was duly considered and it was decided the trading of automobiles should be subject to approval if the trade involves \$1,000 or more. An appropriate change has been made in § 140.5(d)(1) to provide for this.

One commenter suggested that a section be added which exempts

purchases made by BIA employees from Indian-owned businesses that sell goods and services to the Indians at the same terms and prices that are sold to the general public. This suggestion was rejected. The only perceived effect of this proposal would be to provide an exception to the requirement that transactions involving \$1,000 or more must be approved, and we find no justification for doing that.

One commenter proposed elimination of § 140.5(e) to prevent BIA employees from acquiring interests in trust property to eliminate the possibility of speculation in Indian oil and gas rights. The statute, however, provides for acquisitions of rights in trust property, subject to certain specific restrictions. Since the prohibition on commercial trading prevents speculation in Indian oil and gas rights, nothing needs to be done to the proposed rule to prevent such speculation. The comment is rejected.

The Department of the Interior has determined that this document is not a major rule under Executive Order 12291 and certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. § 601 *et seq.*).

The Department of the Interior has determined that this document does not constitute a major Federal action significantly affecting the quality of the human environment under the National Environment Policy Act of 1969.

This rule does not contain any information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. § 3504(h). The primary author of this document is John G. Combs, Bureau of Indian Affairs, Division of Personnel Management, telephone number (202) 343-8718.

List of Subjects in 25 CFR Part 140.

Indians, Business and industry, Penalties.

PART 140—LICENSED INDIAN TRADERS AND BUREAU OF INDIAN AFFAIRS EMPLOYEES CONTRACTING AND TRADING WITH INDIANS

Accordingly, Part 140 of Chapter I of Title 25 of the Code of Federal Regulations is amended as follows:

1. The authority and cross reference sections under the Table of Sections are revised to read as follows:

Authority: Sec. 5, 19 Stat. 200, se. 1, 31 Stat. 1066 as amended; 25 U.S.C. § 261, 262; 94 Stat. 544, 18 U.S.C. § 437; 25 U.S.C. 2 and 9, and 5 U.S.C. § 301, unless otherwise noted.

Cross Reference.

For law and order regulations on Indian Reservations, see part 11 of this Chapter. For regulations pertaining to business practices on Navajo, Hopi and Zuni reservations, see Part 141 of this Chapter. For additional regulation of certain employees trading with Indians, see 43 CFR Part 20.735-28 and 29.

2. Section 140.5 is revised to read as follows:

§ 140.5 Bureau of Indian Affairs employees not to contract or trade with Indians except in certain cases.

(a) Definitions of terms as used in this part:

(1) "Indian" means any member of an Indian tribe recognized as eligible for the services provided by the Bureau of Indian Affairs who is residing on a Federal Indian Reservation, on land held in trust by the United States for Indians, or on land subject to a restriction against alienation imposed by the United States. The term shall also include any such tribe and any Indian owned or controlled organization located on such a reservation or land.

(2) "Bureau" or the "Bureau of Indian Affairs" means the Bureau of Indian Affairs and the Office of the Assistant Secretary for Indian Affairs, both in the Department of the Interior.

(3) "Employee" means an officer, employee, or agent of the Bureau of Indian Affairs.

(4) "Secretary" means the Secretary of the Interior.

(5) "Contract" means any agreement made or under negotiation with any Indian for the purchase, transportation or delivery of goods or supplies.

(6) "Trading" means buying, selling, bartering, renting, leasing, permitting and any other transaction involving the acquisition of property or services.

(7) "Commercial trading" means any trading transaction where an employee engages in the business of buying or selling services or items which he/she is trading.

(b) With the exceptions provided in subsection (b) of section 437 of Title 18, the United States Code, section 437 provides that whoever, being an officer, employee, or agent of the Bureau of Indian Affairs, has (other than as a lawful representative of the United States) any interest, in such officer, employee, or agent's name, or in the name of another person where such officer, employee, or agent benefits or appears to benefit from such interest:

(1) In any contract made or under negotiation with any Indian, for the purchase, transportation or delivery of goods or supplies for any Indian, or

(2) In any purchase or sale of any service or real or personal property (or

any interest therein) from or to any Indian, or colludes with any person attempting to obtain any such contract, purchase, or sale, shall be fined not more than \$5,000 or imprisoned not more than six months or both, and shall be removed from office, notwithstanding any other provision of law concerning termination from Federal employment.

(c) The further subsections of this section authorize certain employees contracting and trading with Indians as authorized by the exceptions in Section 437 of Title 18, United States Code. All such contracting and trading is subject to the express provision of Section 437 that none of the sales or purchases so authorized may be made if the purpose of any such sale, trade, or purchase is that of commercially selling, reselling, trading, or bartering such property.

(d)(1) Under authority granted by section 437(b)(1) of Title 18, United States Code, employees of the Bureau of Indian Affairs may with the approval of an authorized officer of the Bureau, as designated in (d)(2) of this subsection, purchase from or sell to an Indian any service or any real or personal property, not held in trust by the United States or subject to a restriction against alienation imposed by the United States, or any interest in such property. In addition, employees may purchase from Indians without approval from an authorized officer of the Bureau any non-trust or unrestricted personal property for home use or consumption the value of which property does not exceed \$1000. Where the purchase or sale price is less than \$1,000, employees may also purchase motor vehicles for their personal use from Indians or sell their personal motor vehicles to Indians without obtaining approval of such purchases or sales from an authorized officer of the Bureau. Approval must be obtained if the purchase or sale price is \$1,000 or more.

(2) As used in (d)(1) above an authorized officer of the Bureau of Indian Affairs for employees on reservations and in agencies or in field service units shall be the superintendent or other officer in charge of the unit in which the employee is employed. The authorized officer for the superintendent or officer in charge is his or her immediate supervisor. The authorized officer for employees in area offices is the Area Director, and the authorized officer for an Area Director is his or her immediate supervisor. The authorized officer for employees in the Central Office is the Deputy Assistant Secretary—Indian Affairs (Operations).

(e) No employee of the Bureau of Indian Affairs may have any interest in any purchase or sale involving property

or funds which are either held in trust by the United States for Indians or which are purchased, sold, utilized, or received in connection with a contract or grant to an Indian from the Bureau if such employee is employed in the office or installation of the Bureau which recommends, approves, executes, or administers such transaction, grant, or contract on behalf of the United States, except that, as authorized by section 437(b)(1) of Title 18, United States Code an employee of the Bureau may have such an interest if such purchase or sale is approved by an authorized officer of the Bureau, as designated in paragraphs (e) (3) to (5) below, and the conditions in (e) (1) and (2) below are satisfied to the extent to which they are applicable to the transaction concerned:

(1) The conveyance or granting of any interest in property held in trust or subject to restriction against alienation imposed by the United States is otherwise authorized by law.

(2) Trading by employees with Indians which involves property or funds which are either held in trust by the United States or are subject to restrictions against alienation imposed by the United States must be conducted on the basis of sealed bid or public auction. If the trading involves leases or sales of trust or restricted Indian land it must be conducted on the basis of sealed bids. Such requirements for sealed bid or public auction may only be waived by the Assistant Secretary for Indian Affairs on the basis of a full report showing:

(i) The need for the transaction,
(ii) The benefits accruing to both parties,

(iii) That the consideration for the proposed transaction shall be not less than the fair market value of the trust or restricted property or interest therein, unless the employee is involved in a transaction in accordance with 25 CFR § 152.25 (c) or (d) or 25 CFR § 162.5(b) (1), (2), or (3) or the employee is the recipient of a benefit for tribal members for which a uniform charge to all members is made, and

(iv) An affidavit as follows shall accompany each proposed transaction: "I (name) (title), swear (or affirm) that I have not exercised any undue influence nor used any special knowledge received by reason of my employment in the Bureau in obtaining the (grantor's, purchaser's, vendor's) consent to the instant transaction."

(3) The authorized officer of the Bureau for employees employed on reservations, in agencies or service units is one who is not a relative by blood or marriage of the employee, and is not

employed at the employee's reservation, agency or service unit. That officer must also be employed at not less than one grade level higher than such employee at the Washington, District of Columbia, Central Office or at an Area Office other than that with authority over the employee's reservation, agency, or service unit.

(4) The authorized officer of the Bureau for employees employed in Area offices is one who is not a relative by blood or marriage of the employee, is not employed at the employee's area office, and must be employed at not less than one grade level higher than the employee at the Washington, District of Columbia, Central Office.

(5) The authorized officer of the Bureau for employees employed at the Washington, District of Columbia, Central Office is the Secretary.

(f) Except as provided in subsection (b)(2) of Section 437 of Title 18, United States Code as implemented by this section, nothing in the cited law shall be construed as preventing any employee of the Bureau who is an Indian, of whatever degree of Indian blood, from obtaining or receiving any benefit or benefits made available to Indians generally or to any member of his or her particular tribe, under any Act of Congress, nor to prevent any such employee who is an Indian from being a member of or receiving benefits by reason of his or her membership in any Indian tribe, corporation, or cooperative association organized by Indians, when authorized under such rules and regulations as the Secretary or his/her designee has prescribed or shall prescribe.

§ 140.6 [Removed]

3. Section § 140.6 is removed.

Sidney L. Mills,

Acting Deputy Assistant Secretary—Indian Affairs (Operations).

[FR Doc. 84-16402 Filed 8-20-84; 8:45 am]

BILLING CODE 4310-02-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD11 84-40]

Marine Event; Coronado 4th of July Rehearsals and Demonstration

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: This rule will establish Special Local Regulations for the Coronado 4th of July Rehearsals and

Demonstration in Coronado, CA. This event will be held on 4 July 1984, at Glorietta Bay, with rehearsals on 29 June-2 July (3 July inclement weather backup day). These regulations are needed to provide for the safety of life and property on navigable waters during the periods set forth.

EFFECTIVE DATE: These regulations become effective on 29 June 1984 and terminate on 4 July 1984.

FOR FURTHER INFORMATION CONTACT: LTJG Jorge Arroyo, Commander (bb), Eleventh Coast Guard District, 400 Oceangate, Long Beach, California 90822, (213) 590-2331.

SUPPLEMENTARY INFORMATION: A notice of proposed rule making has not been published for these regulations and they are being made effective in less than 30 days from the date of publication. The application to hold this event was not received until 5 May 1984, and there was not sufficient time to publish proposed rules in advance or to provide for a delayed effective date. Nevertheless, interested persons wishing to comment may do so by submitting written comments to the office listed under **FOR FURTHER INFORMATION CONTACT** in this preamble. Commenters should include their name and address, identify this notice CGD11 84-40, and give reasons for their comments. Based on comments received, the regulation may be changed.

Drafting Information

The drafter of this regulation are LTJG Jorge Arroyo, Chief, Boating Affairs Branch, Eleventh Coast Guard District, Project Officer, and CDR M.K. Cain, Project Attorney, Legal Office, Eleventh Coast Guard District.

Discussion of Proposed Regulation

Citizens Committee for the Coronado Fourth of July Celebration "Coronado 4th of July Rehearsals and Demonstration" will be conducted beginning 29 June 1984. This event will have Navy Underwater Demolition Seal teams in water, parachute, and helicopter operations which could pose a hazard to navigation. Therefore, vessels desiring to transit the regulated area may do so only with clearance from a patrolling law enforcement vessel or an event committee boat.

List of Subjects in 33 CFR Part 100

Marine Safety, Navigation (water).

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

Proposed Regulations

In consideration of the foregoing, the Coast Guard proposes to amend Part 100

of Title 33, Code of Federal Regulations, by adding the following § 100.35-11-84-40

§ 100.35-11-84-40 Coronado Fourth of July Rehearsals and Demonstration.

(a) *Regulated area.* That portion of the San Diego Bay from the tip of the marina, Lat 32 degrees 40'43"N, Long 117 degrees 10'20.5"W, NE to Lat 32 degrees 40'48.5"N, Long 117 degrees 10'10.5"W, E along shoreline to Lat 32 degrees 40'43.5"N, Long 117 degrees 10'00"W, E to Lat 32 degrees 40'46"N, Long 117 degrees 09'58"W, S to Lat 32 degrees 40'37.5"N, Long 117 degrees 09'58.5"W, SW to shore at Lat 32 degrees 40'31"N, Long 117 degrees 10'03.5"W; thence NW along shoreline to initial point.

(b) *Effective date.* The regulated area will be closed intermittently to all vessel traffic from 1:30 PM to 4:30 PM on 29 June-2 July (3 July inclement weather backup date) and from 2:00 PM to 4:00 PM on 4 July 1984.

(c) *Special Local Regulations.* (1) No vessels, other than participants, U.S. Coast Guard operated and employed small craft, public vessels, state and local law enforcement agencies and the sponsor's vessels shall enter the regulated area during the above hours, unless cleared for such entry by or through a patrolling law enforcement vessel, or an event committee boat.

(2) When hailed by U.S. Coast Guard operated and employed small craft, law enforcement agencies and/or the sponsor's vessels patrolling the event area, a vessel shall come to an immediate stop. Vessels shall comply with all directions of the designated Regatta Patrol.

(3) These regulations are temporary in nature and shall cease to be in effect at the end of each period set forth.

(46 U.S.C. 454; 49 U.S.C. 1655(b)(1); 49 CFR 1.46(b); 33 CFR 100.35)

Dated: June 15, 1984.

F. P. Schubert,

Rear Admiral, U.S. Coast Guard, Commander, Eleventh Coast Guard District.

[FR Doc. 84-16583 Filed 6-20-84; 8:45 am]

BILLING CODE 4910-14-M

33 CFR Part 100

[CGD 09-84-07]

Special Local Regulations; Chicago Park District Air and Water Show

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: Special local regulations are being adopted for the Chicago Park District Air & Water Show. This event