

The Commission wishes to note that when it initially made available for comment its proposed regulations for certain leverage transactions (48 FR 28668 (June 23, 1983)), § 31.4 contained separate definitions for minimum leverage margin (§31.4(r)) and maintenance leverage margin (§ 31.4(s)). Although the Commission believes the current regulations clearly differentiate between the concepts of minimum leverage margin and maintenance leverage margin, the Commission is amending § 31.4 of the final interim regulations to avoid any confusion that might exist by restoring the separate definitions for minimum leverage margin and maintenance leverage margin. Accordingly, on page 5527 in the third column, § 31.4(r) is revised to read:

"Minimum Leverage Margin" means the amount of funds which a leverage transaction merchant requires a leverage customer to maintain on deposit for each open leverage contract in the leverage customer's account.

Further, on page 5528 in the first column, § 31.4(s) is added to read:

"Maintenance Leverage Margin" means the level to which the funds in a leverage customer's account must be restored after a margin call to the leverage customer has been effected by the leverage transaction merchant.

Copies of the corrected sample format of the illustrative example of a leverage transaction required by § 31.11(a)(3), and of the written confirmation required by § 31.11(k) appear at the end of this document.

Issued in Washington, D.C., on June 15, 1984.

Jane K. Stuckey,

Secretary of the Commission.

Note.—This form will not be shown in the Code of Federal Regulations.
Date: _____

Disclosure Statement, Illustrative Transaction

Commodity _____
Contract Expiration: _____
Leverage Transaction Merchant's Ask Price Per Contract _____
Leverage Transaction Merchant's Bid Price Per Contract _____

BREAK-EVEN CALCULATION FOR A LEVERAGE CONTRACT LEFT OPEN FOR ONE YEAR *

	If contract is repurchased	If contract is liquidated	If delivery is taken
Initial charges.....			
Carrying charges.....			
Bid-ask spread.....			(*)
Price to break-even excluding termination charges.....	(*)	(*)	(*)
Termination charges.....			
Total price to break-even.....			

BREAK-EVEN CALCULATION FOR A LEVERAGE CONTRACT LEFT OPEN FOR ONE YEAR *—Continued

	If contract is repurchased	If contract is liquidated	If delivery is taken
Percentage price change to break-even.....	(*)	(*)	(*)
Price Series to Evaluate the Leverage Contract			
Source of the Price Series			

* Based on current fee schedules, which are subject to change.

* Bid-ask spread not applicable since delivery is taken at contract ask price.

* Equals initial and carrying charges and spread plus bid price of the contract.

* Equals initial and carrying charges plus the ask price per contract. Does not include any expenses which will be incurred privately by the customer reselling the commodity, such as freight, insurance, assay, inspection or discounts typical in the retail market.

* Equals total price to break-even divided by the bid price per contract.

* Equals total price to break-even divided by the ask price per contract.

Note.—This form will not be shown in the Code of Federal Regulations.

If you are a first-time leverage customer you may rescind your first leverage contract purchase subject only to actual price losses but otherwise without penalty for three business days following and including receipt of this confirmation. Actual losses are calculated by subtracting the ask price of the leverage contract at the time of the customer's rescission from the ask price at which the leverage contract was purchased and which appears on this confirmation. To rescind this contract send a telegram to (name and address of LTM) or you may telephone (name of LTM) at (telephone number). If you rescind by telephone, you must also send immediate written affirmation by telegram, by certified letter or by at least equivalent means to the address provided above.

Confirmation Statement

Date: _____
Transaction I.D. Number _____
Commodity _____
Contract Expiration: _____
Leverage Transaction _____
Merchant's Ask Price Per Contract _____
X Number of Contracts _____
Total Value _____

BREAK-EVEN CALCULATION FOR A LEVERAGE CONTRACT LEFT OPEN FOR ONE YEAR *

	If contract is repurchased	If contract is liquidated	If delivery is taken
Initial.....			
Carrying charges.....			
Bid-ask spread.....			(*)
Price to break-even excluding termination charges.....	(*)	(*)	(*)
Termination charges.....			
Total price to break-even.....			
Percentage price change to break-even.....	(*)	(*)	(*)

* Based on current fee schedules, which are subject to ask price.

* Bid-ask spread not applicable since delivery is taken at contract ask price.

* Equals initial and carrying charges and spread plus bid price of the contract.

* Equals initial and carrying charges plus the ask price per contract. Does not include any expenses which will be incurred privately by the customer reselling the commodity,

such as freight, insurance, assay, inspection or discounts typical in the retail market.

* Equals total price to break-even divided by the bid price per contract.

* Equals total price to break-even divided by the ask price per contract.

Margin Requirements (Dollars Per Contract)

Initial Margin _____
Minimum Margin _____
Maintenance Margin _____
Price Series to Evaluate the Leverage Contract _____
Source for the Price Services _____

[FR Doc. 84-16532 Filed 6-20-84; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 82N-0314]

GRAS Status of Peptones

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that peptones are generally recognized as safe (GRAS) as direct human food ingredients. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency.

EFFECTIVE DATE: July 23, 1984.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 3, 1982 (47 FR 54456), FDA published a proposal to affirm that peptones are GRAS for use as direct human food ingredients. 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 peptones and the report of the Select Committee on GRAS Substances (the Select Committee) on peptones are available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents also are available from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status of peptones, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient uses for

these ingredients other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions, so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of peptones recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181) or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

FDA 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 uses for peptones were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of peptones under conditions different from those set forth in this final rule has been waived.

Two comments were received from food manufacturers in response to the proposal. The comments raised three issues. The comments and the agency's responses are as follows:

1. One comment questioned the inclusion of specific protein sources in the proposal for use in the manufacture of peptones. The comment argued that the listing of specific sources was inconsistent with the Select Committee's opinion that peptones derived from enzymatic and acid hydrolysis of food-grade protein sources would not be expected to be toxic, if they were manufactured in accordance with current good manufacturing practice. The comment therefore requested that the proposal be modified to permit any safe and suitable protein source to be used in the manufacture of peptones; or that lactalbumin, egg albumin, whey protein, corn gluten, and wheat gluten be added to the list of protein sources in the regulation.

FDA has thoroughly reviewed this comment and discussed it further in telephone conversations with the company that submitted it. The agency acknowledges that the Select Committee was of the opinion that peptones derived from enzymatic and acid hydrolysis of food-grade protein sources would be expected to be safe. However, the Select Committee also expressed its concern over the potential use of wheat gluten or peptic digests of gluten in the manufacture of peptones because these substances may cause problems for

persons with celiac disease. FDA shared this concern and therefore included in the proposal a description of the specific protein sources reported by the Select Committee as currently used in the manufacture of peptones.

Conversations with the company have revealed that wheat gluten and corn gluten are not used by this company in the manufacture of peptones. The company was primarily interested in the potential use of egg albumin and lactalbumin (also known as whey protein) in the manufacture of peptones for use as nutrient supplements in medical foods. FDA has therefore limited its review to consideration of the GRAS status of peptones derived from these protein sources and of whether peptones may be used as nutrient supplements in food.

Based upon its review of the data and information contained in the Select Committee's report on peptones, the agency concludes that peptones derived from egg albumin and lactalbumin (whey protein) are as safe as those derived from the protein sources originally listed in the proposal. Therefore, the agency is amending the final rule to include egg albumin and lactalbumin (whey protein) among the protein sources for the production of peptones. The agency, however, is denying the comment's request that other protein sources be listed in the regulation because of the concerns expressed by the Select Committee and because the agency has no evidence that any other protein sources are currently in use.

FDA has also considered whether peptones derived from the protein sources listed in this final rule may be safely used as nutrient supplements in food. The agency concludes that there is a large margin of safety for the use of peptones in food and that the additional exposure to these ingredients that will result from their use as nutrient supplements would be well within this safety margin. Accordingly, the agency is adding this technical effect to the final rule.

2. One comment indicated that peptones are currently used in food categories in addition to those that were reported in the proposal: as surface-active agents in fruit and water ices and in processed fruits and fruit juices and as processing aids in gelatins, puddings, and fillings. The comment requested that the agency modify the final rule to affirm as GRAS the use of peptones in these additional food categories.

The agency has reviewed this comment and concurs that peptones may be safely used in the food categories reported. Upon reflection,

FDA has decided that it is not necessary to list in the regulation the food categories in which peptones are used. Both the Select Committee and the agency have concluded that a large margin of safety exists for the use of peptones, and that a reasonably foreseeable increase in the level of consumption of peptones, including that which results from their use in the food categories reported in the comment, will not adversely affect human health. Therefore, the agency has decided to affirm the GRAS status of peptones when they are used under current good manufacturing practice conditions of use in accordance with § 184.1(b)(1) (21 CFR 184.1(b)(1)). To make clear, however, that the affirmation of the GRAS status of peptones is based on the evaluation of currently known uses, the regulation sets forth the technical effects that FDA has evaluated.

3. One comment requested that § 184.1553(a) be amended to include protease enzymes that are derived from safe and suitable microbial sources among the enzymes that can be used in the hydrolysis of the source protein. The comment attached a copy of a 1960 letter from FDA that stated that the use of proteases obtained from nonpathogenic strains of *Bacillus subtilis*, *Aspergillus flavus oxyzae*, or *Aspergillus niger* is GRAS. The comment also noted that the agency had recently affirmed a protease enzyme derived from *B. licheniformis* as GRAS.

The agency agrees that protease enzymes derived from nonpathogenic and nontoxic strains of the four microorganisms mentioned above may be safely used in the manufacture of peptones. Enzymes derived from these microorganisms have been safely used in food production for many years, and the agency concludes that their use in the production of peptones will not present any new toxicological problems. The agency is concerned however that use of the term "safe and suitable" to describe the protease enzymes that can be used in making peptones is too broad and may be subject to misinterpretation. The agency is therefore amending § 184.1553(a) to permit the use of proteolytic enzymes that are considered by FDA to be GRAS or that are regulated as food additives.

In the proposal, FDA stated that it would work with the Committee on Codex Specifications (now known as the Committee on Food Chemicals Codex) of the National Academy of Sciences to develop acceptable specifications for peptones used as direct human food ingredients and would incorporate these specifications into the regulation when

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.

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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