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FEDERAL LABOR RELATIONS AUTHORITY, GENERAL COUNSEL OF THE FEDERAL LABOR RELATIONS AUTHORITY, AND FEDERAL SERVICE IMPASSES PANEL

5 CFR Ch. XIV

Regional Office; Address Change

AGENCY: Federal Labor Relations Authority (including the General Counsel of the Federal Labor Relations Authority) and Federal Service Impasses Panel.

ACTION: Amendment of rules and regulations.

SUMMARY: This document amends Appendix A, paragraph (d)(6) (45 FR 3522) of the rules and regulations of the Federal Labor Relations Authority (Authority), General Counsel of the Federal Labor Relations Authority (General Counsel), and Federal Service Impasses Panel (Panel), published at 5 CFR Part 2400 *et seq.* (1984), to establish a new location and mailing address for the Authority's Dallas Regional Office. The Dallas Regional Office telephone numbers have not been changed.

EFFECTIVE DATE: March 16, 1985.

FOR FURTHER INFORMATION CONTACT: Nancy Anderson Speight, Deputy to the Assistant General Counsel, (202) 382-0811.

SUPPLEMENTARY INFORMATION: Effective January 28, 1980, the Authority, General Counsel and Panel published at 45 FR 3482, January 17, 1980, final rules and regulations to govern the processing of cases by the Authority, General Counsel and Panel under Chapter 71 of Title 5 of the United States Code (5 CFR Part 2400 *et seq.* (1984)). These rules and regulations are required by Title VII of the Civil Service Reform Act of 1978 and are set forth in 5 CFR Part 2400 *et seq.* (1984). Appendix A, Paragraph (d) of the

foregoing rules and regulations sets forth office addresses and telephone numbers of the Regional Directors of the Authority. This amendment sets forth the new location and mailing address of the Dallas Regional Office of the Authority. The Dallas Regional Office telephone numbers have not been changed. Accordingly, in Appendix A to Chapter XIV, paragraph (d)(6) of the Authority, General Counsel, and Panel rules and regulations (5 CFR Part 2400 *et seq.* (1984)) is revised to read as follows:

Appendix A to 5 CFR Ch. XIV—Current Addresses and Geographic Jurisdictions

(d) The Office addresses of Regional Directors of the Authority are as follows:

(6) *Dallas Regional Office*—Federal Office Building, 525 Griffin Street, Suite 926, Dallas, Texas 75202, Telephone: FTS—729-4996, Commercial—(214) 767-4996.

(5 U.S.C. 7134)

Dated: March 1, 1985.

John C. Miller,

General Counsel, Federal Labor Relations Authority.

[FR Doc. 85-5342 Filed 3-5-85; 8:45 am]

BILLING CODE 6727-01-M

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 293 and 294

Personnel Records; Availability of Official Information; Employment (General); Classification Under the General Schedule; Prevailing Rate Systems; Grade and Pay Retention; and Investigations

Correction

In FR Doc. 85-1740, beginning on page 3307 in the issue of Thursday, January 24, 1985, make the following corrections:

PART 293—[CORRECTED]

1. On page 3309, second column, in the last line of the Authority citation for 5 CFR Part 293, "2 CFR" should have read "3 CFR".

§ 293.307 [Corrected]

2. On page 3309, in the third column, the fifth line of § 293.307(a) should have read:

"for additional 60 days (90 days where".

PART 294—[CORRECTED]

§ 294.106 [Corrected]

3. On page 3311, third column, in the ninth line of § 294.106(d), the word "physical" should have read "physician".

§ 294.108 [Corrected]

4. On page 3312, second column, eighth line of § 294.108(e) should have read: "has his or her principal place of business."

BILLING CODE 1505-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 12, 13, 14, 20, 25, 58, 201, 207, 211, 225, 291, 310, 312, 320, 330, 361, 429, 430, and 431

Update of Organizational References

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to update organizational references resulting from a reorganization within the agency.

EFFECTIVE DATE: March 6, 1985.

FOR FURTHER INFORMATION CONTACT: Richard L. Arkin, or Robert D. Bradley, Center for Drugs and Biologics (HFN-364), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 22, 1982 (47 FR 36913), the merger of the Bureau of Drugs and the Bureau of Biologics into the National Center for Drugs and Biologics was announced. In the Federal Register of March 19, 1984 (49 FR 10168), the title was changed to the Center for Drugs and Biologics. In addition, the March 19 document abolished three existing line offices and establishes five new line offices within the Center for Drugs and Biologics to combine similar drugs and biologics functions.

To implement these changes, FDA is amending its regulations by updating them to conform to terms now used in the agency's organizational structure. In addition, FDA is revising 21 CFR 310.503 by changing the name of the Atomic

Energy Commission to the Commission's new title, i.e., the Nuclear Regulatory Commission.

Because these amendments related to internal agency management and personnel and because the amendments are not substantive, the rule is exempt from the notice and comment and delayed effective date requirements of section 553(b) and (d)(3) of the Administrative Procedure Act (5 U.S.C. 553(b) and (d)(3)).

This rule has no economic impact. Therefore, in accordance with section 605(b) of the Regulatory Flexibility Act, FDA certifies that the rule will not have a significant impact on a substantial number of small entities. The rule is related to agency organization, management, and personnel and therefore is exempt from Executive Order 12991.

List of Subjects

21 CFR Part 10

Administrative practice and procedure.

21 CFR Part 12

Administrative practice and procedure.

21 CFR Part 13

Administrative practice and procedure.

21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

21 CFR Part 20

Freedom of information.

21 CFR Part 25

Environmental impact statements.

21 CFR Part 58

Laboratories.

21 CFR Part 201

Drugs, Labeling.

21 CFR Part 207

Drug listing, Drug registration, Reporting requirements.

21 CFR Part 211

Drugs, Manufacturing, labeling, Laboratories, Packaging and containers, Warehouses.

21 CFR Part 225

Animal drugs, Animal feeds, Labeling, Packaging and containers.

21 CFR Part 291

Health professions, Methadone, Recordkeeping and reporting requirements.

21 CFR Part 310

Administrative practice and procedure, Drugs, Medical devices, Recordkeeping and reporting requirements.

21 CFR Part 312

Drugs, Medical research.

21 CFR Part 320

Drugs.

21 CFR Part 330

Over-the-counter drugs.

21 CFR Part 361

Medical research, Prescription drugs, Radiation protection.

21 CFR Part 429

Administrative practice and procedure, Drugs, Insulin, Labeling, Packaging and containers.

21 CFR Part 430

Administrative practice and procedure, Antibiotics.

21 CFR Part 431

Administrative practice and procedure, Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

§§ 10.3, 10.55, 10.75 and 10.100 [Amended]

1. Part 10 is amended by changing "bureau" to "center" and "bureaus" to "centers" wherever they appear in § 10.3 *Definitions* in paragraph (d); § 10.55 *Separation of functions; ex parte communications* in paragraph (b)(2)(i), (ii), and (iii); § 10.75 *Internal agency review of decisions* in the introductory text of paragraph (c) and in paragraph (c)(1) and (2); and § 10.100 *Public calendars* in paragraphs (a)(2)(iii) and (b)(3)(vii) and (4)(iii).

PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

§ 12.50 [Amended]

2. Part 12 is amended in § 12.50 *Advice on public participation in hearings* in paragraphs (d) and (e) by changing "bureau" to "center" and "bureaus" to "centers" wherever they appear.

PART 13—PUBLIC HEARING BEFORE A PUBLIC BOARD OF INQUIRY

§§ 13.10 and 13.25 [Amended]

3. Part 13 is amended by changing "bureau" to "center" wherever it appears in § 13.10 *Members of a Board* in paragraphs (b), (c), and (d) and in § 13.25 *Disclosure of data and information by the participants* in the introductory text of paragraph (a) and in paragraph (a)(3).

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

4. Part 14 is amended in § 14.100 by removing and reserving paragraph (c) and by revising paragraph (b), to read as follows:

§ 14.100 List of standing advisory committees.

(b) *Center for Drugs and Biologics—(1) Allergic Products Advisory Committee.* (i) Date established: July 9, 1984.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of allergenic biological products intended for use in the diagnosis, prevention, or treatment of human diseases.

(2) *Anesthetic and Life Support Drugs Advisory Committee.* (i) Date established: May 1, 1978.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the field of anesthesiology and surgery.

(3) *Anti-Infective Drugs Advisory Committee.* (i) Date established: October 7, 1980.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in infectious diseases.

(4) *Arthritis Advisory Committee.* (i) Date established: April 5, 1974.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in arthritic conditions.

(5) *Blood Products Advisory Committee.* (i) Date established: May 13, 1980.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases.

(6) *Cardiovascular and Renal Drugs Advisory Committee.* (i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in cardiovascular and renal disorders.

(7) *Dermatologic Drugs Advisory Committee.* (i) Date established: October 7, 1980.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the treatment of dermatologic diseases.

(8) *Drug Abuse Advisory Committee.* (i) Date established: May 31, 1978.

(ii) Function: Advises on the scientific and medical evaluation of information gathered by the Department of Health and Human Services and the Department of Justice on the safety, efficacy, and abuse potential of drugs and recommends actions to be taken on the marketing, investigation, and control of such drugs.

(9) *Endocrinologic and Metabolic Drugs Advisory Committee.* (i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in endocrine and metabolic disorders.

(10) *Fertility and Maternal Health Drugs Advisory Committee.* (i) Date established: March 23, 1978.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the practice of obstetrics and gynecology.

(11) *Gastrointestinal Drugs Advisory Committee.* (i) Date established: March 3, 1978.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in gastrointestinal diseases.

(12) *Oncologic Drugs Advisory Committee.* (i) Date established: September 21, 1978.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in treatment of cancer.

(13) [Reserved]

(14) *Peripheral and Central Nervous System Drugs Advisory Committee.* (i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates available data on the safety and

effectiveness of marketed and investigational prescription drugs for use in neurological disease.

(15) *Psychopharmacologic Drugs Advisory Committee.* (i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the practice of psychiatry and related fields.

(16) *Pulmonary-Allergy Drugs Advisory Committee.* (i) Date established: February 17, 1972.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

(17) *Radiopharmaceutical Drugs Advisory Committee.* (i) Date established: August 30, 1967.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the practice of nuclear medicine.

(18) *Vaccines and Related Biological Products Advisory Committee.* (i) Date established: December 31, 1979.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

(c) [Reserved]

* * *

PART 20—PUBLIC INFORMATION

5. Part 20 is amended:

§ 20.44 [Amended]

a. In § 20.44 *Presubmission review of request for confidentiality of voluntarily submitted data or information* in paragraph (a) by changing "Bureau" to "Center".

§ 20.106 [Amended]

b. In § 20.106 *Studies and reports prepared by or with funds provided by the Food and Drug Administration* in paragraph (a)(7) by changing "bureaus" to "centers".

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

§ 25.5 [Amended]

6. Part 25 is amended in § 25.5 *Responsible agency officials* in paragraph (a)(2) by changing "bureau" to "center" wherever it appears.

PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

§ 58.217 [Amended]

7. Part 58 is amended in § 58.217 *Suspension or termination of a testing facility by a sponsor* by changing "Bureau" to "Center" wherever it appears.

PART 201—LABELING

§ 201.59 [Amended]

8. Part 201 is amended in § 201.59 *Effective date of §§ 201.56, 201.57, 201.100(d)(3), and 201.100(e)* in the table in paragraph (a)(3) by changing "HFB-720" to "HFN-825", "HFD-110" to "HFN-110", "HFD-120" to "HFN-120", "HFD-130" to "HFN-810", "HFD-140" to "HFN-815", "HFD-150" to "HFN-150", "HFD-160" to "HFN-160", and "HFD-30" to "HFN-810".

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

9. Part 207 is amended:

a. In § 207.7 by removing and reserving paragraph (b), by changing "Bureau of Medical Devices" to "Center for Devices and Radiological Health" in paragraphs (c) and (d), by changing "Bureau of Drugs" to "Drug Listing Branch (HFN-315), Center for Drugs and Biologics" in paragraph (d), and by revising paragraph (a), to read as follows:

§ 207.7 Establishment registration and product listing for human blood and blood products and for medical devices.

(a) Owners and operators of human blood and blood product establishments shall register and list their products with the Drug Listing Branch, Office of Compliance (HFN-315), Center for Drugs and Biologics, on Form FDA-2830 (Blood Establishment Registration and Product Listing), in accordance with Part 607. Such owners and operators who also manufacture or process other drug products at the same establishment shall, in addition, register and list all such other drug products with the Drug Listing Branch in accordance with this part.

(b) [Reserved]

§ 207.22 [Amended]

b. In § 207.22 *How and where to register and list drugs* in paragraph (a) by changing "Bureau of Drugs, Drug Listing Branch (HFD-315)" to "Drug Listing Branch (HFN-315), Center for

Drugs and Biologics" and in paragraph (b) by changing "Bureau of Drugs, Drug Listing Branch" to "Drug Listing Branch (HFN-315), Center for Drugs and Biologics".

§ 207.37 [Amended]

c. In § 207.37 *Inspection of registrations and drug listings* in paragraph (a) by changing "Bureau of Drugs' Registration Section" to "Drug Listing Branch, Center for Drugs and Biologics," and in paragraphs (a) and (b) by changing "Bureau of Drugs, Registration Section (HFD-315)" to "Drug Listing Branch (HFN-315), Center for Drugs and Biologics".

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

§ 211.176 [Amended]

10. Part 211 is amended in § 211.176 *Penicillin contamination* by changing "Bureau of Drugs (HFD-430)" to "Division of Drug Biology (HFN-170), Center for Drugs and Biologics".

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

§ 225.115 [Amended]

11. Part 225 is amended in § 225.115 *Complaint files* in paragraph (b)(2) by changing "Bureau of" to "Center for".

PART 291—DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS

§ 291.505 [Amended]

12. Part 291 is amended in § 291.505 *Conditions for use of methadone; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts with methadone under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970* in paragraph (h)(1), (2), (3), and (5) by changing "Bureau of Drugs" to "Center for Drugs and Biologics" wherever they appear and in paragraph (k) by changing "Division of Methadone Monitoring (HFD-340)" to "Division of Scientific Investigations (HFN-340)" wherever they appear.

PART 310—NEW DRUGS

13. Part 310 is amended:

§ 310.6 [Amended]

a. In § 310.6 *Applicability of "new drug" or safety or effectiveness findings in drug efficacy study implementation notices and notices of opportunity for hearing to identical, related, and similar drug products* in paragraph (e) by changing "Bureau of Drugs, Office of

Compliance, HFD-300" to "Center for Drugs and Biologics, Office of Compliance, HFN-300".

§ 310.500 [Amended]

b. In § 310.500 *Digoxin products for oral use; conditions for marketing* in paragraph (d) by changing "Bureau of Drugs (HFD-220)" to "Center for Drugs and Biologics (HFN-220)", in paragraph (f) by changing "Bureau of Drugs, Office of Scientific Evaluation, Generic Drug Staff (HFD-107)" to "Center for Drugs and Biologics, Division of Generic Drugs (HFN-230)", and in paragraph (h)(3)(iv) by changing "Bureau of Drugs, Office of Scientific Evaluation (HFD-100)" to "Center for Drugs and Biologics, Office of Drug Research and Review (HFN-100)".

§ 310.501 [Amended]

c. In § 310.501 *Preparations for contraception; labeling directed to the patient* in paragraph (b)(5) by changing "Bureau of Drugs, Division of Metabolic and Endocrine Drug Products (HFD-130)" to "Center for Drugs and Biologics, Division of Metabolism and Endocrine Drug Products (HFN-810)".

§ 310.503 [Amended]

d. In § 310.503 *Requirements regarding certain radioactive drugs* in paragraphs (a), (b), and (c) by changing "Atomic Energy Commission" to "Nuclear Regulatory Commission".

§ 310.509 [Amended]

e. In § 310.509 *Parenteral drug products in plastic containers* in paragraph (e) by changing "(HFD-160), Bureau of Drugs" to "(HFN-160), Center for Drugs and Biologics".

PART 312—NEW DRUGS FOR INVESTIGATIONAL USE

§ 312.1 [Amended]

14. Part 312 is amended in § 312.1 *Conditions for exemption of new drugs for investigational use* in paragraphs (c)(1), (d)(13), and (g) by changing "Bureau of Drugs" to "Office of Drug Research and Review" wherever it appears; in paragraph (g) by changing "Director, Bureau of Biologics" and "Bureau of Biologics" to "Office of Biologics Research and Review"; in paragraph (j) by changing "Bureau of Drugs and the Bureau of Biologics" to "Office of Drug Research and Review and the Office of Biologics Research and Review"; in paragraph (j)(1) by changing "Bureau of Drugs" to "Center for Drugs and Biologics"; and in paragraph (j)(2) and (3) by changing "Director, Bureau of Biologics" to "Office of Biologics Research and Review, Center for Drugs and Biologics".

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

§ 320.30 [Amended]

15. Part 320 is amended in § 320.30 *Inquiries regarding bioavailability requirements and review of protocols by the Food and Drug Administration* in paragraph (c) by changing "Bureau of Drugs" to "Center for Drugs and Biologics" and by changing "(HFD-520)" to "(HFN-220)".

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

16. Part 330 is amended:

§ 330.1 [Amended]

a. In § 330.1 *General conditions for general recognition as safe, effective, and not misbranded* in paragraph (a) by changing "Parts 210, 211, 225, 226 and 229" to "Parts 210 and 211."

§ 330.13 [Amended]

b. In § 330.13 *Conditions for marketing ingredients recommended for over-the-counter (OTC) use under the OTC drug review* in paragraphs (c)(2)(i) and (d)(2)(i) by changing "Bureau of Drugs" to "Center for Drugs and Biologics".

PART 361—PRESCRIPTION DRUGS FOR HUMAN USE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED: DRUGS USED IN RESEARCH

§ 361.1 [Amended]

17. Part 361 is amended in § 361.1 *Radioactive drugs for certain research uses* in paragraph (c)(1) by changing "Bureau of Drugs" to "Center for Drugs and Biologics"; in paragraph (c)(3) by changing "Bureau of Drugs, HFD-150" to "Center for Drugs and Biologics, HFN-150"; in paragraph (c)(4) by changing "Bureau of Drugs" to "Center for Drugs and Biologics" wherever it appears and by changing "HFD-150" to "HFN-150"; and in paragraph (d)(8) by changing "Bureau of Drugs, HFD-150" to "Center for Drugs and Biologics, HFN-150".

PART 429—DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN

§ 429.40 [Amended]

18. Part 429 is amended in § 429.40 *Requests for certification; samples; storage; approvals preliminary to certification* in paragraph (a) by changing "(HFD-410)" to "(HFN-170)".

PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

19. Part 431 is amended:

§ 431.1 [Amended]

a. In § 431.1 *Requests for certification, check tests and assays, and working standards; information and samples required* in paragraph (a) by changing "National Center for Antibiotic Analysis (HFD-430)" to "Division of Drug Biology (HFN-170)".

§ 431.50 [Amended]

b. In § 431.50 *Forms for certification or exemption of antibiotic drugs* by changing "Certification Services Branch (HFD-332)" to "Product Surveillance Branch (HFN-333)".

Effective date. This regulation is effective March 6, 1985.

[Sec. 701(a), 52 Stat. 1555 (21 U.S.C. 371(a))]

Dated: February 26, 1985.

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-5329 Filed 3-5-85; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 184

[Docket No. 82G-0207]

Direct Food Substances Affirmed as Generally Recognized as Safe; Low Erucic Acid Rapeseed Oil**Correction**

In FR Doc. 85-2000 beginning on page 3745 in the issue of Monday, January 28, 1985, make the following corrections:

1. On page 3747, first column, paragraph designated as (1), line thirteen, "without" should appear between "weight" and "adverse".
2. On page 3751, first column, third line from the bottom, "d-HBDH" should read "α-HBDH".

BILLING CODE 1505-01-M

21 CFR Part 184

[Docket No. 82N-0259]

Wheat Gluten, Corn Gluten, and Zein; Affirmation of GRAS Status

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that wheat gluten, corn gluten, and zein 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: April 5, 1985.

FOR FURTHER INFORMATION CONTACT:

Kenneth J. Falci, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 12, 1983 (48 FR 31887), FDA published a proposal to affirm that wheat gluten, corn gluten, and zein are GRAS for use as direct human food ingredients. FDA published this proposal in accordance with its announced 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 wheat gluten, corn gluten, and zein and the report of the Select Committee on GRAS Substances (the Select Committee) on wheat gluten, corn gluten, and zein were made 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 are also available for public purchase from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status of wheat gluten, corn gluten, and zein, FDA gave public notice that it was unaware of any prior-sanctioned food 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 these ingredients 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 wheat gluten, corn gluten, and zein were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for the use of these ingredients under conditions different from those set forth in this final rule has been waived.

FDA received four comments in response to the proposal. The comments

and the agency's response to them are as follows:

1. One comment, from a person suffering from celiac disease, stated that labeling foods as "gluten free" would be a helpful label for packaged food products.

FDA discussed in its proposal (48 FR 31888) that persons with celiac disease are unable to ingest gluten from wheat and from some other sources without intestinal upset. However, FDA also noted that these same individuals are able to consume without ill-effects gluten derived from corn, rice, potato, and other foods. Because glutens do not always initiate intestinal upset in persons with celiac disease, the agency finds that labeling packaged foods as "gluten free" would not be as desirable as actually identifying on the food label the source of the gluten that is used in the food. Under 21 CFR 101.4(a), wheat gluten and other gluten sources must be identified by name when they are used in food. FDA believes, therefore, that the labeling already required is adequate to alert the public and protect gluten-sensitive individuals.

2. One comment stated that corn gluten is being investigated for use as a nutrient supplement in food and requested that the ingredient be listed for this technical effect in the final rule. The comment also requested that a cross-reference indicating that zein is produced from corn gluten be added to the proposed regulation for corn gluten.

The agency notes that wheat gluten is used as a nutrient supplement in food. Because corn gluten has a nutrient profile similar to that of wheat gluten, the agency believes that it is reasonable to conclude that corn gluten may also be used for this technical effect. Additionally, FDA concludes that adequate data exist in the Select Committee's report for it to find that the use of corn gluten as a nutrient supplement in food is safe and for it to affirm that corn gluten is GRAS for this use. Therefore, the agency is including the use of corn gluten as a nutrient supplement in § 184.1321(c)(1) (21 CFR 184.1321(c)(1)).

The agency does not agree that the corn gluten regulation should state that it is used to produce zein. The regulation for zein already states that it is made from corn gluten. Inclusion of this statement in the zein regulation is consistent with FDA's practice of describing how and from what sources regulated ingredients are obtained. The agency does not consider it necessary, however, to include a list of the products that may be manufactured from an ingredient in the regulation for that

ingredient. Therefore, the agency is not including the requested cross-reference in the regulation for corn gluten.

3. One comment stated that corn gluten is produced as a byproduct in the manufacture of corn syrups from dry milled corn. The comment stated that corn gluten is produced during the in-situ conversion of the starch in whole or various fractions of dry milled corn to corn syrups.

The agency agrees that this method has been used to prepare corn gluten and has incorporated it into § 184.1321(a).

4. One comment stated that four additional technical effects for wheat gluten should be added to the regulation for that ingredient. These additional technical effects are formulation aid, processing aid, stabilizer and thickener, and surface-finishing agent. The comment contained a substantial amount of information demonstrating that wheat gluten is currently being used for each of these technical effects.

The agency has reviewed the use information submitted in the comment and has determined that wheat gluten is currently used for the additional technical effects reported in this comment. Additionally, the agency concludes that adequate safety data exist in the Select Committee's report to assure that these uses are safe, and that they may be affirmed as GRAS. Therefore, the agency is incorporating these additional technical effects in this final rule.

The agency is also making two minor editorial changes in the regulation for corn gluten to correct errors in the spelling of "glutelin" and "gluten".

In the proposal, FDA stated that it would work with the Committee on Food Chemicals Codex of the National Academy of Sciences to develop acceptable specifications for corn gluten, wheat gluten, and zein used as direct food ingredients and would incorporate those specifications into the regulations when they were developed. To date, however, work on the specifications is still incomplete. Until the specifications are developed, these ingredients for direct food uses must comply with the descriptions in the respective regulations and be of food-grade purity (21 CFR 182.1(b)(3) and 170.30(h)(1)).

The agency had 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 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, FDA has previously analyzed the potential economic 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 the Order. The agency has not received any new information or comments that would alter its previous determination.

The agency's findings 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 threshold assessments which may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

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) and redelegated to the Center for Food Safety and Applied Nutrition (21 CFR 5.61; see 49 FR 48183; December 11, 1984), Part 184 is amended as follows:

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

1. By adding new § 184.1321, to read as follows:

§ 184.1321 Corn gluten.

(a) Corn gluten (CAS Reg. No. 86071-96-3), also known as corn gluten meal, is the principal protein component of corn endosperm. It consists mainly of zein and glutelin. Corn gluten is a byproduct of the wet milling of corn for starch. The gluten fraction is washed to remove residual water soluble proteins. Corn gluten is also produced as a byproduct during the conversion of the starch in

whole or various fractions of dry milled corn to corn syrups.

(b) FDA is developing food-grade specifications for corn gluten in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

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

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter and a texturizer as defined in § 170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

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

2. By adding new § 184.1322, to read as follows:

§ 184.1322 Wheat gluten.

(a) Wheat gluten (CAS Reg. No. 8002-80-0) is the principal protein component of wheat and consists mainly of gliadin and glutenin. Wheat gluten is obtained by hydrating wheat flour and mechanically working the sticky mass to separate the wheat gluten from the starch and other flour components. Vital gluten is dried gluten that has retained its elastic properties.

(b) FDA is developing food-grade specifications for wheat gluten in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

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

(1) The ingredient is used as a dough strengthener as defined in § 170.3(o)(6) of this chapter; a formulation aid as defined in § 170.3(o)(14) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; a processing aid as defined in § 170.3(o)(24) of this chapter; a stabilizer and thickener as defined in

§ 170.3(o)(28) of this chapter; a surface-finishing agent as defined in § 170.3(o)(30) of this chapter; and a texturizing agent as defined in § 170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

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

3. By adding new § 184.1984, to read as follows:

§ 184.1984 Zein.

(a) Zein (CAS Reg. No. 9010-86-6) is one of the components of corn gluten. It is produced commercially by extraction from corn gluten with alkaline aqueous isopropyl alcohol containing sodium hydroxide. The extract is then cooled, which causes the zein to precipitate.

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

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

(1) The ingredient is used as a surface-finishing agent as defined in § 170.3(o)(30) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

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

Effective date. This regulation is effective April 5, 1985.

[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: February 15, 1985.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-5424 Filed 3-5-85; 8:45 am]

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ENVIRONMENTAL PROTECTION

AGENCY

21 CFR Part 561

Animal Drugs, Feeds, and Related Products; Tolerances for Pesticides in Feeds Administered by the Environmental Protection Agency; 3,6-Bis(2-Chlorophenyl)-1,2,4,5-Tetrazine

[FAP 3H5312/R743; FRL-2790-7]

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule extends an established feed additive regulation to permit residues of the acaricide 3,6-Bis(2-chlorophenyl)-1,2,4,5-tetrazine in or on apple pomace. This extension of the regulation will permit the continued testing and gathering of additional data on the pesticide and marketing of apple pomace in connection with an experimental use program. The extension was requested by the Nor-Am Chemical Co.

EFFECTIVE DATE: Effective on March 16, 1985.

ADDRESS: Written objections, identified by the document control number [FAP 3H5412/R743], may be submitted to the: Hearing Clerk (A-110), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Jay Ellenberger, Product Manager (PM) 12, Registration Division (TS-767C), Environmental Protection Agency, Rm 202, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-2386).

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the *Federal Register* of September 12, 1984 (49 FR 35767), which established a regulation to permit residues of the acaricide 3,6-Bis(2-chlorophenyl)-1,2,4,5-tetrazine in or on apple pomace in accordance with an experimental use program to expire March 15, 1985.

At the request of the Nor-Am Chemical Co., Wilmington, DE 19803, the regulation is extended to expire March 16, 1986, to permit the continued testing and gathering of additional data on the pesticide and marketing of apple pomace in connection with an experimental use program.

The data and other relevant material submitted in support of the regulation

have been evaluated and discussed in the final rule document of September 12, 1984.

The pesticide is considered useful for the purpose for which the regulation is sought. It is concluded that the pesticide may be safely used in the prescribed manner when such use is in accordance with the label and labeling registered pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, (86 Stat. 973, 89 Stat. 751, U.S.C. 135(a) *et seq.*) and is established as set forth below.

The Office of Management and Budget has exempted this rule from the requirements of section 3 Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-534, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new food or feed additive levels, or conditions for safe use of additives, or raising such food or feed additive levels do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the *Federal Register* of May 4, 1981 (46 FR 24945).

List of Subjects in 21 CFR Part 561

Feed additives, Pesticides and pests.

[Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 346(c)(1))]

Dated: February 25, 1985.

Steven Schatzow,

Director, Office of Pesticide Programs.

PART 561—[AMENDED]

Therefore, 21 CFR 561.92 is revised to read as follows:

§ 561.92 3,6-Bis(2-chlorophenyl)-1,2,4,5-tetrazine.

A tolerance of 20.0 parts per million is established for residues of the acaricide 3,6-Bis(2-chlorophenyl)-1,2,4,5-tetrazine in apple pomace resulting from application of the acaricide to apples. Such residues may be present therein only as a result of the application of the acaricide in accordance with the provisions of the experimental use permit number 45639-EUP-14 that expires March 15, 1986.

[FR Doc. 85-5349 Filed 3-5-85; 8:45 am]

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