Technical Note: Fermenters include bioreactors, chemostats, and continuous-flow systems.

c. Centrifugal separators capable of the continuous separation of pathogenic microorganisms, without the propagation of aerosols, and having all of the following characteristics:

c.1. A flow rate greater than 100 liters per hour;

c.2. Components of polished stainless steel or titanium;

c.3. Double or multiple sealing joints within the steam containment area; *and*

c.4. Capable of *in situ* steam sterilization in a closed state.

Technical Note: Centrifugal separators include decanters.

d. Cross (tangential) flow filtration equipment capable of continuous separation of pathogenic microorganisms, viruses, toxins, and cell cultures without the propagation of aerosols, having all of the following characteristics:

d.1. Equal to or greater than 5 square meters;

d.2. Capable of *in situ* sterilization.

e. Steam sterilizable freeze-drying equipment with a condenser capacity greater than 50 kgs of ice in 24 hours but less than 1,000 kgs;

f. Equipment that incorporates or is contained in P3 or P4 containment housing, as follows:

f.1. Independently ventilated protective full or half suits;

f.2. Class III biological safety cabinets or isolators with similar performance standards;

g. Chambers designed for aerosol challenge testing with microorganisms, viruses, or toxins and having a capacity of 1 m^3 or greater.

Dated: September 22, 2000.

R. Roger Majak,

Assistant Secretary for Export Administration.

[FR Doc. 00–25068 Filed 10–2–00; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 91N–0101, 91N–0098, 91N–0103, and 91N–100H]

RIN 0910–AA19

Food Labeling: Health Claims and Labeling Statements; Dietary Fiber and Cancer; Antioxidant Vitamins and Cancer; Omega-3 Fatty Acids and Coronary Heart Disease; Folate and Neural Tube Defects; Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking its regulations codifying the agency's decision not to authorize the use of health claims for four substance-disease relationships in the labeling of foods, including dietary supplements: Dietary fiber and cancer, antioxidant vitamins and cancer, omega-3 fatty acids and coronary heart disease, and the claim that 0.8 milligram (mg) of folate in dietary supplement form is more effective in reducing the risk of neural tube defects than a lower amount in conventional food. This action is being taken in response to a decision of the U.S. Court of Appeals for the D.C. Circuit invalidating these regulations and directing FDA to reconsider whether to authorize the four health claims. This action will result in the removal of the regulations but does not constitute FDA authorization of the four claims. FDA is completing its reconsideration of the claims and expects to issue decisions on all four claims by October 10, 2000.

DATES: This rule is effective October 3, 2000.

FOR FURTHER INFORMATION CONTACT: James E. Hoadley, Center for Food Safety and Applied Nutrition (HFS–832), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5429.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 6, 1993, FDA issued final rules announcing its decision not to authorize the use of health claims for four substance-disease relationships in the labeling of conventional foods. (See 58 FR 2537 (dietary fiber and cancer); 58 FR 2622 (antioxidant vitamins and cancer); 58 FR 2682 (omega-3 fatty acids and coronary heart disease); and 58 FR 2606 (folic acid [1] and neural tube defects[2])). Soon after, FDA proposed in the **Federal Register** of October 14, 1993 (58 FR 53296), not to authorize use of three of the four claims in the labeling of dietary supplements. In October 1993, after further review of evidence on the relationship between folate and reduced risk of neural tube defects, FDA proposed to authorize a health claim for this relationship (58 FR 53254, October 14, 1993); however, the agency proposed not to allow such claims to include a statement that folate from one source is more effective in reducing the risk of neural tube defects than folate from another source. Both proposals became final by operation of law on December 31, 1993. (See 59 FR 395, January 4, 1994 (dietary fiber and cancer, antioxidant vitamins and cancer, and omega-3 fatty acids and coronary heart disease); 59 FR 433, January 4, 1994 (folate and neural tube defects).) FDA's decisions not to authorize these four claims are codified in § 101.71(a) (21 CFR 101.71(a)) (dietary fiber and cancer); § 101.71(c) (antioxidant vitamins and cancer); § 101.71(e) (omega-3 fatty acids and coronary heart disease); and § 101.79(c)(2)(i)(G) (21 CFR 101.79(c)(2)(i)(G)) (claims comparing effectiveness of folate from different sources).

Several dietary supplement marketers and nonprofit organizations that had submitted comments during FDA's health claims rulemakings filed suit in Federal district court on constitutional and statutory grounds seeking, among other things, authorization to make the following health claims for use in the labeling of dietary supplements: ''Consumption of fiber may reduce the risk of colorectal cancer,'' ''Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer,'' ''Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease,'' and ''0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form.'' The district court ruled for FDA in all respects

[1] In its original health claim evaluation, FDA used the term ''folic acid'' to describe this B vitamin. Later, the agency decided that the broader term ''folate'' was more scientifically accurate because that term encompasses both synthetic and naturally occurring forms of the vitamin, whereas folic acid refers only to the synthetic form (see 58 FR 53254 at 53257 through 53258 and 53280, October 14, 1993). Accordingly, this rule uses the term ''folate.'' The two terms may be used interchangeably in food labeling.

[2] Neural tube defects are birth defects of the brain or spinal cord. Spina bifida and anencephaly are the most common types of neural tube defects.

(*Pearson* v. *Shalala*, 14 F. Supp. 2d 10 (D.D.C. 1998)); however, the U.S. Court of Appeals for the D.C. Circuit reversed the district court's decision. The court of appeals held the regulations codifying FDA's decision not to authorize the four health claims invalid and instructed FDA to reconsider the four health claims (*Pearson* v. *Shalala*, 164 F.3d 650 (D.C. Cir. 1999)).

In the Nutrition Labeling and Education Act of 1990, Congress made health claims for dietary supplements subject to a procedure and standard to be established by FDA (see section 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(5)(D)). FDA adopted the same procedure for health claims in dietary supplement labeling that Congress had prescribed for health claims in the labeling of conventional foods (see section 403(r)(3) and (r)(4) of the act). This procedure requires the evidence supporting a health claim to be presented to FDA for review before the claim may appear in labeling. Unless and until FDA adopts a regulation authorizing the claim, a dietary supplement bearing the claim is subject to regulatory action as a misbranded food (see section 403(r)(1)(B) of the act, a misbranded drug (see section 502(f)(1) of the act (21 U.S.C. 352(f)(1)), and as an unapproved new drug (see section 505(a) of the act (21 U.S.C. 355(a)).

Recently, the U.S. District Court for the District of Columbia denied the *Pearson* plaintiffs' motion for a preliminary injunction granting them immediate permission to make the four health claims that FDA is reconsidering. In their motion, the plaintiffs argued that because the court of appeals had invalidated the regulations codifying FDA's decision not to authorize the four claims, the claims should be permitted in dietary supplement labeling if accompanied by disclaimers suggested by the court of appeals. The district court rejected this argument. The court's decision said in part that a preliminary injunction was not in order because the plaintiffs may not bypass FDA's pre-clearance process for health claims. ''Plaintiffs' fatal assumption is that the Court of Appeals' invalidation of the regulations allows them to now make their health claims with disclaimers, without any further pre-clearance by FDA. It does not. Invalidation of the regulations merely puts plaintiffs back at square one, which means they must again go through the pre-clearance process * * *.'' (*Pearson* v. *Shalala*, No. Civ. A. 95–1865, 2000 WL 767584, at *2 (D.D.C. May 24, 2000)).

Thus, while FDA is revoking the regulations codifying its original decision not to authorize the four health claims that were challenged in *Pearson*, such claims still may not be used in labeling pending reconsideration of these claims by FDA. FDA expects to complete its reconsideration of the four claims and issue a decision on each claim by October 10, 2000.

II. Effective Date

The Administrative Procedure Act and FDA regulations provide that an agency may dispense with notice-and-comment rulemaking procedures when the agency for good cause finds that such procedures are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(3)(B); § 10.40(e)(1) (21 CFR 10.40(e)(1))). Because this final rule is being issued in response to a court order, FDA finds that notice and comment are unnecessary. In addition, the Commissioner of Food and Drugs finds good cause under 5 U.S.C. 553(d)(3) and § 10.40(c)(4)(ii) to make this final rule effective upon publication.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

§ 101.71 [Amended]

2. Section 101.71 *Health claims: claims not authorized* is amended by removing paragraphs (a), (c), and (e); and by redesignating paragraph (b) as paragraph (a), and paragraph (d) as paragraph (b).

§ 101.79 [Amended]

3. Section 101.79 *Health claims: Folate and neural tube defects* is amended by removing paragraph (c)(2)(i)(G), and by redesignating paragraph (c)(2)(i)(H) as (c)(2)(i)(G).

Dated: September 25, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–25352 Filed 10–2–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 36

Contracts Under the Indian Self-Determination Act; Removal of Regulations

AGENCY: Indian Health Service, HHS.

ACTION: Final rule.

SUMMARY: The Indian Health Service (IHS) is eliminating regulations on contracts under the Indian Self-Determination Act as mandated by Executive Order 12866 to streamline the regulatory process and enhance the planning and coordination of new and existing regulations.

EFFECTIVE DATE: October 3, 2000.

FOR FURTHER INFORMATION CONTACT: Leslie M. Morris, Director, Division of Regulatory and Legal Affairs, Indian Health Service, Suite 450, 12300 Twinbrook Parkway, Rockville, MD 20852; telephone (301) 443–1116. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On June 24, 1996, The Department of Health and Human Services (HHS) and the Department of the Interior (DOI) issued joint regulations authorized by section 107 of the Indian Self-Determination and Education Assistance Act (ISDA), Public Law 93–638, as amended, 25 U.S.C. 450k. These joint regulations, published in the **Federal Register** on June 24, 1996, and codified at 25 CFR part 900, replaced Department regulations codified at 42 CFR part 36, subpart I, ''Contracts under the ISDA''; 48 CFR section 352.280–4, ''Contracts awarded under the ISDA''; 48 CFR section 352.380–4, ''Contracts awarded under the ISDA''; and 48 CFR subpart 380.4, ''Contracts awarded under the ISDA''; because they are no longer necessary for the Administration of the IHS Program.

Section 107(b) of the ISDA provides in pertinent part that ''the secretary is authorized to repeal any regulation inconsistent with the provisions of this act.'' The HHS has proposed at 64 FR 1344 to revise 48 CFR, Chapter 3, to streamline and simplify its acquisition regulations (HHSRA) in accordance with the directions of the National Performance Review. In so doing, the sections of 48 CFR liminated by the joint rule (25 CFR part 900) issued by the HHS and the DOI would be removed. Therefore, the IHS proposed at 65 FR 4797 the elimination of only Subpart I of 42 CFR part 36. No comments were received in response to the proposed rule. The proposed rule is converted to a final rule without change.