DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 100, 101, 103, 104, 105, 109, 137, 161, 163, 182, 186, 197, 200, 250, 310, 500, 505, 507, 508, 510, 570, 601, 620, 630, 640, 650, 660, 680, 700, and 801

[Docket Nos. 95N–0310, 95N–310B, 95N–310F, 95N–310R, and 95N–310V]

Revocation of Certain Regulations; Opportunity for Public Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revoke certain regulations that are obsolete or no longer necessary to achieve public health goals. These regulations have been identified for revocation as the result of a page-by-page review of the agency's regulations. This regulatory review is in response to the Administration's ''Reinventing Government'' initiative which seeks to streamline government to ease the burden on regulated industry and consumers.

DATES: Submit comments by January 11, 1996. The agency is proposing that any final rule that may issue based upon this proposal become effective 30 days after its publication in the Federal Register.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Regarding general information on FDA's ''reinventing initiative'': Lisa M. Helmanis, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3480.

Regarding food and cosmetic regulations: Corinne Howley, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 200 C. St., Washington, DC 20004, 202–205–4272.

Regarding drug regulations: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–366), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

Regarding veterinary medicine regulations: Kristi O. Smedley, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1737.

Regarding biologic regulations: Timothy W. Beth, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 208529–1448, 301–594–3074.

Regarding medical device and radiological health regulations: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765.

SUPPLEMENTARY INFORMATION:

I. Background

On March 4, 1995, President Clinton announced plans for the reform of the Federal regulatory system as part of the Administration's ''Reinventing Government'' initiative. In his March 4 directive, the President ordered all Federal agencies to conduct a page-by-page review of all of their regulations and to ''eliminate or revise those that are outdated or otherwise in need of reform.'' The first results of FDA's efforts in implementing the President's plan are contained in this Federal Register document. This document announces the regulations that FDA is proposing to eliminate. In a separate, upcoming issue of the Federal Register, FDA intends to revise a number of regulations in response to the President's initiative.

The following is a section-by-section analysis of the regulations that FDA is proposing to revoke. Each of FDA's Centers has conducted an analysis of the regulations in its respective area of responsibility. These analyses are set forth in the numerical order in which they appear in the Code of Federal Regulations (CFR).

The sections that FDA is proposing to eliminate from the CFR follow.

II. Section-by-Section Analysis

A. Center for Food Safety and Applied Nutrition

All comments submitted in response to the regulations in this section, and pertaining to the Center for Food Safety and Applied Nutrition should be identified with docket number 95N–310F.

1. Section 100.120 *Artificially red-dyed yellow varieties of sweet potatoes* (21 CFR 100.120). This section addresses the adulteration of sweet potatoes with artificial coloring. This information can be more appropriately given as a statement of policy and need not appear in the CFR.

2. Section 100.130 *Combinations of nutritive and nonnutritive sweeteners in ''diet beverages''* (21 CFR 100.130). This section authorizes the mixture of nutritive sweeteners and saccharin to produce a product more acceptable to consumers. This administrative ruling became obsolete with the advent of additional nonnutritive sweeteners.

3. Section 100.135 *Disposition of incubator reject eggs* (21 CFR 100.135). This section addresses the introduction of adulterated eggs into interstate commerce. This information can be more appropriately given as a statement of policy and need not appear in the CFR.

4. Section 100.140 *Label declaration of salt in frozen vegetables* (21 CFR 100.140). This section addresses the failure to disclose salt on the label of frozen vegetables. This section is unnecessary because coverage of this information in § 101.4 *Designation of ingredients* (21 CFR 101.4) is sufficient.

5. Section 100.145 *Notice to packers of comminuted tomato products* (21 CFR 100.145). This section addresses tomato rot. This administrative ruling can be more appropriately given as guidance and need not appear in the CFR.

6. Section 100.150 *Notice to packers and shippers of shelled peanuts* (21 CFR 100.150). This section addresses failure to bear labeling on the bag as required by the Federal Food, Drug, and Cosmetic Act (the act). This section is unnecessary because coverage in §§ 101.3 *Identity statement*, 101.5 *Name and place of business of packer or distributor*, and 101.105 *Statement of net quantity of contents* is sufficient.

7. Section 100.160 *Tolerances for moldy and insect-infested cocoa beans* (21 CFR 100.160). This information can be more appropriately given as a statement of policy and need not appear in the CFR.

8. Section 101.33 *Label declaration of D-erythroascorbic acid when it is an ingredient of a fabricated food* (21 CFR 101.33), is unnecessary because coverage in § 101.4 *Designation of ingredients* is sufficient.

9. Section 101.103 *Petitions requesting exemptions from or special requirements for label declaration of ingredients* (21 CFR 101.103) is duplicative. The procedures in § 10.30 *Citizen petition* (21 CFR 10.30) are sufficient.

10. Part 103—Quality Standards for Foods With No Identity Standards (21 CFR part 103). The definition (103.3) and general principles (103.5)

regulations in this part are no longer needed because there are no substantive regulations in this part; the agency has proposed to establish a standard of identity for bottled water in § 165.110 (21 CFR 165.110), and recodify the quality standard for bottled water (103.35).

11. Section 104.19 *Petitions* (21 CFR 104.19). This section addresses the submission of petitions for a nutritional quality guideline for a class of foods and is duplicative; the procedures in § 10.30 are sufficient.

12. Section 105.67 *Label statement relating to food for use in the diet of diabetics* (21 CFR 105.67), is no longer in accord with current dietary advice for persons with diabetes. The regulations that FDA adopted in response to the Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535), and the new ingredient labeling regulations that FDA adopted, should ensure that food labels contain sufficient information to assist diabetics in making educated food choices.

13. Section 105.69 *Foods used to regulate sodium intake* (21 CFR 105.69) is in conflict with section 403(q) of the act because it allows for optional nutrition labeling of sodium, whereas the act requires that this information be disclosed.

14. Section 109.5 *Petitions* (21 CFR 109.5). This section which addresses the submission of petitions for tolerances, regulatory limits, and action levels, is duplicative. The procedures in § 10.30 are sufficient.

FDA is proposing to revoke the following regulations because they are either obsolete, unnecessary, or because they otherwise serve no public interest. In a future issue of the Federal Register, the agency will seek public comment on the remaining Food Standards not contained below.

15. Section 137.230 *Corn Grits* (21 CFR 137.230).

16. Section 137.235 *Enriched corn grits* (21 CFR 137.235).

17. Section 137.240 *Quick grits* (21 CFR 137.240).

18. Section 137.245 *Yellow grits* (21 CFR 137.245).

19. Section 161.131 *Extra large oysters* (21 CFR 161.131).

20. Section 161.132 *Large oysters* (21 CFR 161.132).

21. Section 161.133 *Medium oysters* (21 CFR 161.133).

22. Section 161.134 *Small oysters* (21 CFR 161.134).

23. Section 161.135 *Very small oysters* (21 CFR 161.135).

24. Section 161.137 *Large Pacific oysters* (21 CFR 161.137).

25. Section 161.138 *Medium Pacific oysters* (21 CFR 161.138).

26. Section 161.139 *Small Pacific oysters* (21 CFR 161.139).

27. Section 161.140 *Extra small Pacific oysters* (21 CFR 161.140).

28. Section 163.150 *Sweet cocoa and vegetable fat coating* (21 CFR 163.150).

29. Section 163.153 *Sweet chocolate and vegetable fat coating* (21 CFR 163.153).

30. Section 163.155 *Milk chocolate and vegetable fat coating* (21 CFR 163.155).

31. Subpart F— Dietary Supplements of part 182 (21 CFR part 182). The 56 regulations under this subpart were made obsolete by the Dietary Supplement Health and Education Act of 1994 (Pub. L. 103–417), which exempted dietary ingredients of dietary supplements from food additive and GRAS regulations.

32. Section 186.1025 *Caprylic acid* (21 CFR 186.1025) is duplicative as the ingredient is already listed as generally recognized as safe under § 184.1025 (21 CFR 184.1025).

33. Part 197—Seafood Inspection Program (21 CFR part 197). The 28 regulations under this part are obsolete and no longer used by the agency or industry.

34. Section 700.10 *Shampoo preparations containing eggs as one of the ingredients* (21 CFR 700.10). Coverage in section 701.1 is sufficient.

B. Center for Drug Evaluation and Research

All comments submitted in response to the regulations in this section, and pertaining to the Center for Drug Evaluation and Research, should be identified with docket number 95N–310.

1. Section 200.100 *Use of ox bile from condemned livers from slaughtered animals in the manufacture of drugs* (21 CFR 200.100). This section was issued in response to a question from the Department of Agriculture concerning whether it would violate the act to release, for use in drug manufacturing, ox bile obtained from the condemned livers of slaughtered animals. This section states that ox bile treated with sodium hydroxide and properly labeled may be released. This specific advice about nonviolation of the act can be more appropriately given in the form of a policy statement than a regulation and need not appear in the CFR.

2. Section 200.101 *Suprarenal glands from hog carcasses prior to final inspection* (21 CFR 200.101). This section specifies how suprarenal glands from hog carcasses which are intended for use in drug manufacturing should be treated in order to eliminate microorganisms or toxins. This specific guidance about the processing of a drug component can be more appropriately given in the form of a policy statement than a regulation and need not appear in the CFR.

3. Section 250.104 *Status of salt substitutes under the Federal Food, Drug, and Cosmetic Act* (21 CFR 250.104). In 1949, FDA announced that it would regard all salt substitutes as new drugs which required new drug applications (NDA's). This regulation states that FDA no longer regards all salt substitutes as new drugs, and provides that FDA will respond to requests as to whether a particular salt substitute requires an NDA. The agency opinion about the new drug status of a particular category of food additives can be more appropriately given in the form of a policy statement than a regulation and need not appear in the CFR.

4. Section 250.203 *Status of fluoridated water and foods prepared with fluoridated water* (21 CFR 250.203). This section was issued in response to questions about the use of fluorine. The regulation states that the addition of fluorine to public water supplies is not actionable under the act as long as the Environmental Protection Agency (EPA) limits are observed. Similarly, the use of fluoridated water in commercially prepared foods is not actionable unless the process involves a significant concentration of fluorine from the water. This specific advice about nonviolation of the act can be more appropriately given in the form of a policy statement than a regulation and need not appear in the CFR.

5. Section 310.101 *FD&C Red No. 4; procedure for discontinuing use in new drugs for ingestion; statement of policy* (21 CFR 310.101). This section describes the conditions under which products with approved NDA's may discontinue using FD&C Red No. 4 and substitute a permitted color additive.This section is unnecessary because there are no longer any ingested new drugs that use FD&C Red No. 4.

6. Section 310.304 *Drugs that are subjects of approved new drug applications and that require special studies, records, and reports* (21 CFR 310.304). This section relates only to methadone. It states that although there is a need for further safety and effectiveness data on methadone, methadone may be distributed under certain controlled conditions. Section 310.304 has been superseded by §§ 291.501 and 291.505 and therefore is obsolete.

C. Center for Veterinary Medicine

All comments submitted in response to the regulations in this section, and

pertaining to the Center for Veterinary Medicine, should be identified with docket number 95N–310V.

1. Section 500.49 *Chlorofluorocarbon propellants* (21 CFR 500.49). This section prohibits the use of chlorofluorocarbons as propellants in self-pressurized containers in animal drugs. Chlorofluorocarbons are prohibited by the Clean Air Act Amendments of 1990 (42 U.S.C. 7671) and can no longer be marketed for this use. This section is unnecessary because coverage in § 2.125 (21 CFR 2.125) of this prohibition is sufficient.

2. Section 505.3 *Warnings on animal drugs intended for administration to diseased animals* (21 CFR 505.3). This section states that no warning or caution statements recommended for use in the labeling of animal drugs intended for administration to diseased animals shall be construed to suggest or imply that a product of diseased animals is suitable for food use. This provision cautions against misuse of language in § 505.20 which is now being withdrawn and is, therefore, unnecessary.

3. Section 505.20 *Recommended animal drug warning and caution statements* (21 CFR 505.20). This section provides recommended animal drug warning and caution statements for specific drugs. The statements provided are voluntary label statements that do not contain requirements and need not appear in the CFR.

4. Part 507—Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (21 CFR part 507). This part contains the criteria that apply in determining whether the facilities, methods, practices, and controls used by the commercial processor in the manufacture, processing, and packing of low-acid foods for animals in hermetically sealed containers are operated or administered in a manner adequate to protect the public health. Part 507 is identical to part 113 (21 CFR part 113), which applies to human foods. Therefore, the agency is proposing to remove part 507, and proposing to add a new § 500.23 to state that the provisions in part 113 apply to animal foods.

5. Part 508—Emergency Permit Control (21 CFR part 508) covers the requirements and issuance of emergency control permits for the manufacturer or packer of thermally processed low-acid foods packaged in hermetically sealed containers. Part 508 is identical to part 108 (21 CFR part 108), which applies to human foods. Therefore, the agency is proposing to remove part 508, and proposing to add a new § 500.24 to state that the provisions in part 108 apply to food intended for animals.

6. Section 510.120 *Suspension of approval of new-drug applications for certain diethylstilbestrol and diethylstilbestrol-containing drugs* (21 CFR 510.120). This section provides the suspension of approval of the seven listed diethylstilbestrol (DES)-containing animal drug products. There are no approved new animal drug applications for DES-containing products. This regulation is obsolete and should be deleted.

7. Section 510.200 *Export of new animal drug* (21 CFR 510.200). This section states that to export a new animal drug the product must comply with regulations issued under section 512 of the act (21 U.S.C. 360b). This provision has been superseded by changes in the act (see 21 U.S.C. 382).

8. Section 510.310 *Records and reports for new animal drugs approved before June 20, 1963* (21 CFR 510.310). This section sets out separate requirements for recordkeeping and reporting to the agency for drugs approved prior to June 20, 1963. These requirements are outdated and inaccurate. The agency believes it is appropriate to have the same recordkeeping and reporting requirements for drugs approved before 1963.

9. Section 510.413*Chloroform used as an ingredient (active or inactive) in animal drug products* (21 CFR 510.413). This section prohibits the use of chloroform as an ingredient in animal drugs and provides certain requirements for products that contain chloroform that must be met by October 3, 1977. Chloroform is no longer used as an ingredient in any animal drug formulations. Drug formulation is reviewed by the manufacturing chemists in FDA's Center for Veterinary Medicine (CVM), and this regulation is no longer necessary.

10. Section 570.22 *Safety factors to be considered* (21 CFR 570.22). This section sets out a proposed safety factor to be used by CVM scientists when there is not justification of a different safety factor. The safety factors provided in the regulations are scientifically obsolete for food additives intended for animals and are best handled within the review process.

D. Center For Biologics Evaluation and Research

All comments submitted in response to the regulations in this section, and pertaining to the Center for Biologics Evaluation and Research should be identified with docket number 95N–310B.

Many of the regulations proposed for deletion are regulations that duplicate standards that are also specified in product licenses required for biological products intended for human use under section 351 of the Public Health Service Act (42 U.S.C. 262). The additional standards regulations and the individual product licenses provide standards regarding the required methods of manufacture and testing of biological products. In some of these cases, the additional standard regulations are therefore duplicative and unnecessary for the following reasons: The codification by regulation of many of the additional standards for biologicals sometimes does not allow for the flexibility necessary to keep abreast of technological advances in science. For many years, because of the potential for impeding scientific progress, FDA has not codified specific additional standards for licensed biological products, but instead has set the required standards in the product licenses. The deletion of these regulations will increase regulatory flexibility by allowing industry and the agency to more readily use and incorporate current scientific technology in the manufacture and regulation of licensed biological products.

FDA is proposing to retain most of the additional standards for human blood and blood products because many facilities that manufacture these products are intrastate facilities that are registered with FDA but do not hold product licenses that specify the methods of manufacture and testing to be used. Instead of submitting clinical data and license applications to FDA for approval, these intrastate manufacturers of blood and blood products must manufacture their products in conformance with the additional standards in the regulations which have been demonstrated to result in safe, pure, and potent products. Also, these additional standards for blood and blood components function in lieu of safety and efficacy data in blood components and source plasma applications for licensure. Therefore, FDA has determined that it is in the best interest of the public health to retain most of the additional standards for blood and blood products. In this proposed rule FDA is proposing to delete clearly unnecessary regulations. FDA is currently reviewing other biologics regulations, the potential deletion or revision of which involves issues of greater regulatory complexity. As a result of this review, FDA may, in the future, propose to delete or significantly revise other biologics regulations.

1. Section 601.30 *Licenses required; products for controlled investigation only* (21 CFR 601.30). The requirements of this section are contained in section 351 of the Public Health Service Act and in section 505 of the act and in 21 CFR parts 50, 56, 58, and 312. Therefore, § 601.30 is duplicative and unnecessary.

2. Section 601.31 *Procedure* (21 CFR 601.31). The licensing procedures for foreign establishments and products are the same as those that the agency follows for domestic establishments and products, which are codified in 21 CFR part 601, subparts A through C. Therefore, this regulation is duplicative and unnecessary.

3. Section 601.32 *Form of License* (21 CFR 601.32). The form of licenses for foreign establishments and products, including the availability for inspection requirement is the same as the form for domestic establishments and products. Therefore, this regulation is duplicative and unnecessary.

4. Part 620—Additional Standards for Bacterial Products (21 CFR part 620). The 31 regulations in this part are more appropriately specified in the product license. As currently written, these regulations can be too restrictive for certain products because they specify particular methodologies or standards when alternatives may be available that provide the same level of assurance of safety, purity and potency. Allowing the product standards to be specified in the product license will give manufacturers the flexibility to improve their products and make appropriate changes to their methods of manufacture. Therefore, these regulations may be unduly restrictive and are duplicative and unnecessary.

5. Part 630—Additional Standards for Viral Vaccines (21 CFR part 630). The 42 regulations in this part are more appropriately specified in the product license. As currently written, these regulations can be too restrictive for certain products because they specify particular methodologies or standards when alternatives may be available that provide the same level of assurance of safety, purity and potency. Allowing the additional standards to be specified in the product license will allow manufacturers the flexibility to improve their products and make appropriate changes to their methods of manufacture. Therefore, these regulations may be unduly restrictive and are duplicative and unnecessary.

6. Part 640, Subpart K—Measles Immune Globulin (Human) (21 CFR part 640, subpart). There has been no manufacturer licensed for measles immune globulin in the United States since 1982. These five regulations would be more appropriately specified in a product license if manufacture should resume. Therefore, these regulations may be unduly restrictive and are obsolete and unnecessary.

7. Part 650—Additional Standards for Diagnostic Substances for Dermal Tests (21 CFR part 650). These 12 regulations may be unduly restrictive and are duplicative and unnecessary.

8. Part 660, Subpart K—Limulus Amebocyte Lysate (21 CFR part 660, Subpart K). These six regulations for limulus amebocyte lysate products are specified in the product license. Therefore, these regulations may be unduly restrictive and are duplicative and unnecessary.

9. Part 680, Subpart B—Trivalent Organic Arsenicals (21 CFR part 680, Subpart B). There has been no manufacturer licensed for trivalent organic arsenical products in the United States since 1956. These seven regulations would be more appropriately specified in a product license if manufacture should resume. Therefore, these regulations may be unduly restrictive and are obsolete and unnecessary.

10. Part 680, Subpart C—Blood Group Substances (21 CFR part 680, Subpart C). The seven regulations for these products are specified in the product license. Therefore, these regulations may be unduly restrictive and are duplicative and unnecessary.

E. Center for Devices and Radiological Health

All comments submitted in response to the regulations in this section, and pertaining to the Center for Devices and Radiological Health should be identified with docket number 95N–310R.

1. Section 801.403 *Specific medical devices; recommended warning and caution statements* (21 CFR 801.403). This regulation recommends certain warning and caution statements for: denture reliners, pads, and cushions; denture repair kits; infrared generators (including hearing pads); insulin syringes; mechanical massagers and vibrators; steam or turkish baths; and ultraviolet generators. This section does not contain requirements and, therefore, need not appear in the CFR.

2. Section 801.408 *Pessaries for intracervical and intrauterine use* (21 CFR 801.408). This section contains information that can be more appropriately given as statements of policy and need not appear in the CFR.

3. Section 801.427 *Professional and patient labeling for intrauterine contraceptive devices* (21 CFR 801.427). This regulation is no longer necessary because these devices are no longer being marketed. If any intrauterine contraceptive devices are approved for marketing in the future, the labeling will be approved during the premarket approval process.

III. Economic Impact

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed deletions have no compliance costs and do not result in any new requirements, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(9) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Request for Comments

Interested persons may, on or before January 11, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number assigned to the particular center(s) involved. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 100

Administrative practice and procedure, Food labeling, Food packaging, Foods, Intergovernmental relations.

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 103

Beverages, Bottled water, Food grades and standards.

21 CFR Part 104

Food grades and standards, Frozen foods, Nutrition.

21 CFR Part 105

Dietary Foods, food grades and standards, Food labeling, Infants and children.

21 CFR Part 109

Food packaging, Foods, Polychlorinated biphenyls (PCB's).

21 CFR Part 137

Cereal(s) (food).

21 CFR Part 161

Food grades and standards, Frozen foods, Seafood.

21 CFR Part 163

Cacao products, Food grades and standards.

21 CFR Part 182

Food ingredients, Food packaging, Spices and flavorings.

21 CFR Part 186

Food ingredients, Food packaging.

21 CFR Part 197

Food grades and standards, Reporting and recordkeeping requirements, Seafood.

21 CFR Part 200

Drugs, Prescription drugs.

21 CFR Part 250

Drugs.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Polychlorinated biphenyls (PCB's).

21 CFR Part 505

Animal drugs, Labeling, Over-the-counter drugs.

21 CFR Part 507

Animal foods, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 508

Animal foods.

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 570

Animal feeds, Animal foods, Food additives.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

21 CFR Part 620

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 630

Biologics, Labeling.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 650

Biologics.

21 CFR Part 660

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 680

Biologics, Blood, Reporting and recordkeeping requirements.

21 CFR Part 700

Cosmetics, Packaging and containers.

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.)* and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 100, 101, 103, 104, 105, 109, 137, 161, 163, 182, 186, 197, 200, 250, 310, 500, 505, 507, 508, 510, 570, 601, 620, 630, 640, 650, 660, 680, 700, and 801 be amended as follows:

PART 100—GENERAL

1. The authority citation for 21 CFR part 100 continues to read as follows:

Authority: Secs. 201, 301, 307, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 337, 342, 343, 348, 371).

§ 100.120 [Removed]

2. Section 100.120 *Artificially red-dyed yellow varieties of sweet potatoes* is removed from subpart G.

§ 100.130 [Removed]

3. Section 100.130 *Combinations of nutritive and nonnutritive sweeteners in ''diet beverages''* is removed from subpart G.

§ 100.135 [Removed]

4. Section 100.135 *Disposition of incubator reject eggs* is removed from subpart G.

§ 100.140 [Removed]

5. Section 100.140 *Label declaration of salt in frozen vegetables* is removed from subpart G.

§ 100.145 [Removed]

6. Section 100.145 *Notice to packers of comminuted tomato products* is removed from subpart G.

§ 100.150 [Removed]

7. Section 100.150 *Notice to packers and shippers of shelled peanuts* is removed from subpart G.

§ 100.160 [Removed]

8. Section 100.160 *Tolerances for moldy and insect-infested cocoa-beans is removed from subpart G.*

PART 101—FOOD LABELING

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

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

§ 101.33 [Removed]

10. Section 101.33 *Label declaration of D-erythroascorbic acid when it is an ingredient of a fabricated food* is removed from subpart B.

§ 101.103 [Removed]

11. Section 101.103 *Petitions requesting exemptions from or special requirements for label declaration of ingredients* is removed from subpart G.

PART 103—QUALITY STANDARDS FOR FOODS WITH NO IDENTITY STANDARDS

Part 103 [Removed]

12–13. Part 103 is removed.

PART 104—NUTRITIONAL QUALITY GUIDELINES FOR FOODS

14. The authority citation for 21 CFR part 104 continues to read as follows:

Authority: Secs. 201, 403, 701(a) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321, 343, 371(a)).

§ 104.19 [Removed]

15. Section 104.19 *Petitions* is removed from subpart A.

PART 105—FOODS FOR SPECIAL DIETARY USE

16. The authority citation for 21 CFR part 105 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 411, 701, 721 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 350, 371, 379e).

§ 105.67 [Removed]

17. Section 105.67 *Certain label statements relating to food for use in the diet of diabetics* is removed from subpart B.

§ 105.69 [Removed]

18. Section 105.69 *Foods used to regulate sodium intake* is removed from subpart B.

PART 109—UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD-PACKAGING MATERIAL

19. The authority citation for 21 CFR part 109 continues to read as follows:

Authority: Secs. 201, 306, 402, 406, 408, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 342, 346, 346a, 348, 371).

§ 109.5 [Removed]

20. Section 109.5 *Petitions* is removed.

PART 137—CEREAL FLOURS AND RELATED PRODUCTS

21. The authority citation for 21 CFR part 137 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

§ 137.230 [Removed]

22. Section 137.230 *Corn grits* is removed.

§ 137.235 [Removed]

23. Section 137.235 *Enriched corn grits* is removed.

§ 137.240 [Removed]

24. Section 137.240 *Quick grits* is removed.

§ 137.245 [Removed]

25. Section 137.245 *Yellow grits* is removed.

PART 161—FISH AND SHELLFISH

26. The authority citation for 21 CFR part 161 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

§ 161.131 [Removed]

27. Section 161.131 *Extra large oysters* is removed from subpart B.

§ 161.132 [Removed]

28. Section 161.132 *Large oysters* is removed from subpart B.

§ 161.133 [Removed]

29. Section 161.133 *Medium oysters* is removed from subpart B.

§ 161.134 [Removed]

30. Section 161.134 *Small oysters* is removed from subpart B.

§ 161.135 [Removed]

31. Section 161.135 *Very small oysters* is removed from subpart B.

§ 161.137 [Removed]

32. Section 161.137 *Large Pacific oysters* is removed from subpart B.

§ 161.138 [Removed]

33. Section 161.138 *Medium Pacific oysters* is removed from subpart B.

§ 161.139 [Removed]

34. Section 161.139 *Small Pacific oysters* is removed from subpart B.

§ 161.140 [Removed]

35. Section 161.140 *Extra small Pacific oysters* is removed from subpart B.

PART 163—COCAO PRODUCTS

36. The authority citation for 21 CFR part 163 continues to read as follows:

Authority: Secs. 201, 301, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 341, 343, 348, 371, 379e).

§ 163.150 [Removed]

37. Section 163.150 *Sweet cocoa and vegetable fat coating* is removed.

§ 163.153 [Removed]

38. Section 163.153 *Sweet chocolate and vegetable fat coating* is removed.

§ 163.155 [Removed]

39. Section 163.155 *Milk chocolate and vegetable fat coating* is removed.

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

40. The authority citation for 21 CFR part 182 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

Subpart F [Removed]

41. Subpart F, consisting of §§ 182.5013 through 182.5997, is removed.

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

42. The authority citation for 21 CFR part 186 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

§ 186.1025 [Removed]

43. Section 186.1025 *Caprylic acid* is removed from subpart B.

PART 197—SEAFOOD INSPECTION PROGRAM

Part 197 [Removed]

44–45. Part 197 is removed.

PART 200—GENERAL

46. The authority citation for 21 CFR Part 200 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 508, 515, 701, 704, 705 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360e, 371, 374, 375).

§ 200.100 [Removed]

47. Section 200.100 *Use of ox bile from condemned livers from slaughtered animals in the manufacture of drugs* is removed.

§ 200.101 [Removed]

48. Section 200.101 *Suprarenal glands from hog carcasses prior to final inspection* is removed.

PART 250—SPECIAL REQUIREMENTS FOR SPECIFIC HUMAN DRUGS

49. The authority citation for 21 CFR part 250 continues to read as follows:

Authority: Secs. 201, 306, 402, 502, 503, 505, 601(a), 602(a) and (c), 701, 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 342, 352, 353, 355, 361(a), 362(a) and (c), 371, 375(b)).

§ 250.104 [Removed]

50. Section 250.104 *Status of salt substitutes under the Federal Food, Drug, and Cosmetic Act* is removed.

§ 250.203 [Removed]

51. Section 250.203 *Status of fluoridated water and foods prepared with fluoridated water* is removed.

PART 310—NEW DRUGS

52. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

§ 310.101 [Removed]

53. Section 310.101 *FD&C Red No. 4; procedure for discontinuing use in new drugs for ingestion; statement of policy* is removed.

§ 310.304 [Removed]

54. Section 310.304 *Drugs that are subjects of approved new drug applications and that require special studies, records, and reports* is removed.

PART 500—GENERAL

55. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: Secs. 201, 301, 402, 403, 409, 501, 502, 503, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371).

56. Section 500.23 is added to subpart B to read as follows:

§ 500.23 Thermally processed low-acid foods packaged in hermetically sealed containers.

The provisions of part 113 of this chapter shall apply to the manufacture, processing or packing of low-acid foods in hermetically sealed containers, and intended for use as food for animals.

57. Section 500.24 is added to subpart B to read as follows:

§ 500.24 Emergency permit control.

The provisions of part 108 of this chapter shall apply to the issuance of emergency control permits for the manufacturer or packer of thermally processed low-acid foods packaged in hermetically sealed containers, and intended for use as food for animals.

§ 500.49 [Removed]

58. Section 500.49 *Chlorofluorocarbon propellants* is removed from subpart B.

Part 505—INTERPRETIVE STATEMENTS RE: WARNINGS ON ANIMAL DRUGS FOR OVER-THE-COUNTER SALE

Part 505 [Removed]

59–61. Part 505 is removed.

PART 507—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

Part 507 [Removed]

62–63. Part 507 is removed.

PART 508—EMERGENCY PERMIT CONTROL

Part 508 [Removed]

64–65. Part 508 is removed.

PART 510—NEW ANIMAL DRUGS

66. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

§ 510.120 [Removed]

67. Section 510.120 *Suspension of approval of new-drug applications for certain diethylstilbestrol and diethylstilbestrol-containing drugs* is removed from subpart B.

§ 510.200 [Removed]

68. Subpart C, consisting of § 510.200, is removed and reserved.

§ 510.310 [Removed]

69. Section 510.310 *Records and reports for new animal drugs approved before June 20, 1963* is removed from subpart D.

§ 510.413

70. Section 510.413 *Chloroform used as an ingredient (active or inactive) in animal drug products* is removed from subpart E.

PART 570—FOOD ADDITIVES

71. The authority citation for 21 CFR part 570 continues to read as follows:

Authority: Secs. 201, 401, 402, 408, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 346a, 348, 371).

§ 570.22

72. Section 570.22 *Safety factors to be considered* is removed from subpart B.

PART 601—LICENSING

73. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 513–516, 518–520, 701, 704, 721, 801, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381); secs. 215, 301, 351, 352 of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461).

§ 601.30 [Removed]

74. Section 601.30 *Licenses required; products for controlled investigation only* is removed.

§ 601.31 [Removed]

75. Section 601.31 *Procedure* is removed.

§ 601.32 [Removed]

76. Section 601.32 *Form of license* is removed.

PART 620—ADDITIONAL STANDARDS FOR BACTERIAL PRODUCTS

Part 620 [Removed]

77–78. Part 620 is removed.

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINES

Part 630 [Removed]

79–80. Part 630 is removed.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

81. The authority citation for 21 CFR part 640 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

Subpart K [Removed and Reserved]

82. Subpart K, consisting of §§ 640.110 through 640.114, is removed and reserved.

PART 650—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR DERMAL TESTS

Part 650 [Removed]

83–84. Part 650 is removed.

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

85. The authority citation for 21 CFR part 660 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

Subpart K [Removed]

86. Subpart K, consisting of §§ 660.100 through 660.105, is removed.

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

87. The authority citation for 21 CFR part 680 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

88. The heading for Subpart A—Allergenic Products is removed.

Subpart B [Removed]

89. Subpart B, consisting of §§ 680.10 through 680.16, is removed.

Subpart C [Removed]

90. Subpart C, consisting of §§ 680.20 through 680.26, is removed.

PART 700—GENERAL

91. The authority citation for 21 CFR part 700 continues to read as follows:

Authority: Secs. 201, 301, 502, 505, 601, 602, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 352, 355, 361, 362, 371, 374).

§ 700.10 [Removed]

92. Section 700.10 *Shampoo preparations containing eggs as one of the ingredients* is removed.

PART 801—LABELING

93. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 507, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374).

§ 801.403 [Removed]

94. Section 801.403 *Specific medical devices; recommended warning and caution statements* is removed from subpart H.

§ 801.408 [Removed]

95. Section 801.408 *Pessaries for intracervical and intrauterine use* is removed from subpart H.

§ 801.427 [Removed]

96. Section 801.427 *Professional and patient labeling for intrauterine contraceptive devices* is removed from subpart H.

Dated: October 6, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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