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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter 1

[Docket No. 02N–0434]

Withdrawal of Certain Proposed Rules and Other Proposed Actions; Notice of Intent

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intent to withdraw certain advance notice of proposed rulemakings (ANPRMs), proposed rules, and other proposed actions that published in the **Federal Register** more than 5 years ago. These proposals rules are no longer considered viable candidates for final action at this time. FDA is taking this action to reduce its regulatory backlog and focus its resources on current public health issues. The FDA's actions are part of an overall regulatory reform strategy initiated by HHS Secretary Tommy G. Thompson.

DATES: Submit written or electronic comments by [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

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FOR FURTHER INFORMATION CONTACT: Lisa M. Helmanis, Regulations Policy and Management Staff (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

SUPPLEMENTARY INFORMATION: On June 8, 2001, Secretary Thompson announced his regulatory reform initiative designed to reduce regulatory burdens in health care and respond faster to the concerns of health care providers, State, and local governments and individual Americans who are affected by HHS rules. In December of 2001 the Secretary announced the membership of his Regulatory Reform Committee designed to carry out his initiative. In November of 2002 the Committee released its final report with over 255 specific recommendations for simplifying, streamlining and generally reducing the regulatory burden while continuing to require accountability by those doing business with HHS and its agencies. Over 25 of the recommendations have been adopted and the Secretary charged the Office of the Assistant Secretary for Planning and Evaluation to continue the efforts of the Regulatory Reform Committee. FDA's continuing efforts to withdraw regulations that have been proposed but not finalized are part of this overall initiative.

I. Background

In 1990, FDA began a comprehensive review of its regulations process that included a review of the backlog of advance notices of proposed rulemaking, notices of proposed rulemaking, and other notices for which no final action or withdrawal notice had been issued. In the **Federal Register** of August 28, 1991 (56 FR 42668), FDA announced its intent to withdraw 115 proposed rules published before December 31, 1985, that had never been finalized and invited comment on its intent. In the **Federal Register** of December 30, 1991 (56 FR

67440), FDA issued its first notice withdrawing 89 of those outstanding proposed rules. Again, in the **Federal Register** of January 19, 1993 (58 FR 4953), FDA announced its intent to withdraw 10 proposed rules that had never been finalized and invited comment on its intent. In the **Federal Register** of January 20, 1994 (59 FR 3042), the agency withdrew an additional 9 outstanding proposed rules.

Once again, FDA has reviewed its pending proposed rules and other notices that published in the **Federal Register** more than 5 years ago, and for which no final rule or notice of withdrawal has been issued. The agency has identified 84 such proposed rules and other actions that should be formally withdrawn. Included in this current list are 19 proposed rules that were included in the original 1991 list, but at that time, the agency decided to defer its decision to withdraw or finalize them until a later date. As with the other proposals it intends to withdraw, FDA believes that it is no longer appropriate to continue these rulemakings. These 19 proposed rules are identified in table 1 of this document.

As with the 1991 review, the agency undertook this most recent review because it believes that the backlog of pending proposals dilutes its ability to concentrate on higher priority regulations that are mandated by statute or necessary to address current public health issues. Because of the agency's limited resources and changing priorities, FDA has been unable to consider, in a timely manner, the issues raised by the comments on these proposals and either complete the action on them or withdraw the proposals. Additionally, because many of the proposals have become outdated in the time that has elapsed since their publication, the agency would need to obtain further comment on them before proceeding to final action. FDA has determined that

the proposals identified in this document are lower in priority than those on the Unified Agenda and the Regulatory Plan. It is unlikely that the agency will have sufficient resources in the foreseeable future to further consider or prioritize these proposed rules. Although not required to do so by the Administrative Procedure Act or by regulations of the Office of the Federal Register, the agency believes the public interest is best served by withdrawing these 84 proposals. In some instances, the agency has already completed action on alternatives, e.g., the issuance of guidance or inclusion of provisions in related regulations, that have obviated the need to complete the proposed action.

If the agency does withdraw these proposals, that action would not preclude the agency from reinstituting proceedings to issue rules concerning the issues addressed in the proposals listed in table 1 of this document. Should FDA decide to undertake such a rulemaking sometime in the future, it will re-propose the actions and provide new opportunities for comment. For some proposals, the agency already has plans to institute new proceedings. Further, interested persons may submit a citizen petition requesting that the agency initiate rulemaking on any of the issues covered by the proposed rules that FDA intends to withdraw.

The agency advises that in some cases the preambles of these proposals may still reflect the current position of FDA on the matter addressed. In addition, withdrawal of a proposal is not intended to affect whatever utility the preamble statements may currently have as indications of FDA's position on a matter at the time the proposal was published.

Therefore, for the reasons set forth previously, and under the Federal Food, Drug, and Cosmetic Act, the agency announces its intent to withdraw the

following documents, published in the **Federal Register** on the dates indicated in table 1:

TABLE 1.

Title	Docket No.	FR publication date and cite
Radioactive Drugs, Including Biological Products	75N–0069	July 25, 1975, 40 FR 31314
Conditions for Use of Methadone	75N–0125	April 29, 1976, 41 FR 17922
Pasteurized Milk Ordinance and Interstate Milk Shippers	75N–0243	May 5, 1975, 40 FR 19513
Oral Contraceptive Drug Products; Physician and Patient Labeling	75N–0304	December 7, 1976, 41 FR 53633
Penicillin Streptomycin Powder; Penicillin—Dihydrostreptomycin Powder; Proposed Revocation of Certification Provision	75N–0374	July 9, 1976, 41 FR 28313
Conditions for Use of Methadone; Physiologic Dependence, Staffing, and Urine Testing Requirements	76N–0098	April 29, 1976, 41 FR 17926
Sorbic Acid and Its Salts; Proposed Affirmation and Deletion of GRAS Status	77G–0379[1]	March 10, 1978, 43 FR 9823
Butylated Hydroxytoluene; Use Restrictions	77N–0003[1]	May 31, 1977, 42 FR 27603
Color Additives; Proposed Use of Abbreviations for Labeling Foods, Drugs, Cosmetics, and Medical Devices	77N–0009 and 78P–0164	June 6, 1985, 50 FR 23815
Brown and Yellow Mustard and Their Derivatives; Proposed Affirmation of GRAS Status as Direct Human Food Ingredients	77N–0033[1]	August 26, 1977, 42 FR 43092
Acrylonitrile Copolymers Intended for Use in Contact With Food; Proposed Rulemaking	77N–0078	March 11, 1977, 42 FR 13562
Gelatin; Affirmation of GRAS Status as a Direct and Indirect Human Food Ingredient	77N–0232[1]	November 11, 1977, 42 FR 58763 and May 12, 1993, 58 FR 27959 (Tentative final rule)
New Animal Drugs for Use in Animal Feeds; Animal Feeds Containing Penicillin and Tetracycline	77N–0318	January 20, 1978, 43 FR 3032
Ethylene Oxide, Ethylene Chlorohydrin, and Ethylene Glycol; Proposed Maximum Residue Limits and Maximun Daily Levels of Exposure	77N–0424[1]	June 23, 1978, 43 FR 27474
Label Designation of Ingredients in Cheese and Cheese Products	77P–0146	July 19, 1984, 49 FR 29242
Food Chemicals Codex Monographs; Opportunity for Public Comment on Revisions	78N–0072	April 18, 1978, 43 FR 16413
Cellulose Derivatives; Affirmation of GRAS Status	78N–0144[1]	February 23, 1979, 44 FR 10751
Tocopherols and Derivatives; Proposed Affirmation of GRAS Status for Certain Tocopherols and Removal of Certain Others From GRAS Status as Direct Human Food Ingredients	78N–0213[1]	October 27, 1978, 43 FR 50193
Chlortetracycline-Sulfamethazine Tablets	78N–0247	September 22, 1978, 43 FR 43036
Phosphates; Proposed Affirmation of and Deletion From GRAS Status as Direct and Human Food Ingredients	78N–0272	December 18, 1979, 44 FR 74845
Biotin; Proposed Affirmation of GRAS Status	78N–0308[1]	January 14, 1983, 48 FR 1739
Lard and Lard Oil; Proposed Affirmation of GRAS Status as Indirect Human Food Ingredients	78N–0336[1]	May 18, 1979, 44 FR 29102
Glycerin; Affirmation of GRAS Status as a Direct Human Food Ingredient	78N–0348[1]	February 8, 1983, 48 FR 5758
Medical Devices, Sponges for Internal Use	78N–1074	November 28, 1976, 43 FR 55697
Medical Devices; Classification of Powered Myoelectric Biofeedback Equipment	78N–1183	August 28, 1979, 44 FR 50464
Porcine burn dressing	78N–2670	January 19, 1982, 47 FR 2828
Food Ingredient Labeling, Emulsifiers, and Stabilizers (Carob Bean Gum); Exemptions	78P–0052	April 17, 1985, 50 FR 15177
Sodium Dithionite and Zinc Dithionite; Proposed Affirmation of GRAS Status	79N–0095[1]	January 25, 1980, 45 FR 6117 and September 17, 1982, 47 FR 41137 (Tentative final rule)
Current Good Manufacturing Practice in Manufacture Processing, Packing, or Holding; Proposed Exemption From Active Ingredient Identity and Strength Testing for Homoeopathic Drug Products	79P–0265	April 1, 1983, 48 FR 14003
Hydrochloric Acid; Proposed Affirmation of GRAS Status as a Direct Human Food Ingredient	80N–0148[1]	April 26, 1984, 49 FR 17966

TABLE 1.—Continued

Title	Docket No.	FR publication date and cite
Cheeses and Related Cheese Products; General Standard of Identity for "Certain Other Cheeses"	80N–0373	April 23, 1984, 49 FR 17018
Caffeine; Deletion of GRAS Status, Proposed Declaration That No Prior Sanction Exists, and Use on an Interim Basis Pending Additional Study	80N–0418[1]	October 21, 1980, 45 FR 69817
Policy for Regulating Carcinogenic Chemicals in Food and Color Additives; Advance Notice of Proposed Rulemaking	81N–0281	April 2, 1982, 47 FR 14464
Magnesium Gluconate, Potassium Gluconate, Sodium Gluconate, Zinc Gluconate, and Gluconic Acid; Proposed GRAS Status as Direct and Indirect Human Food Ingredients	81N–0382	October 29, 1982, 47 FR 49028
Protein Hydrolysates and Enzymatically Hydrolyzed Animal (Milk Casein) Protein; Proposed GRAS Status	82N–0006[1]	December 8, 1983, 48 FR 54990
Zinc Salts; Proposed Affirmation of GRAS Status	82N–0167[1]	October 26, 1982, 47 FR 47441
Regenerated Collagen; Proposed GRAS Status as a Direct Human Food Ingredient	82N–0219[1]	April 26, 1983, 48 FR 18833
Ascorbic Acid and Its Sodium and Calcium Salts, Erythorbic Acid and Its Sodium Salt, and Ascorbyl Palmitate; Proposed Affirmation of GRAS Status and Removal of Calcium Ascorbate From the List of GRAS Ingredients	82N–0246[1]	January 14, 1983, 48 FR 1735
Caffeine in Nonalcoholic Carbonated Beverages	82N–0318	May 20, 1987, 52 FR 18923
Common or Usual Names for Nonstandardized Foods; Diluted Fruit or Vegetable Juice Beverages	82N–0389	June 1, 1984, 49 FR 22831
Reclassification of Electroconvulsive Therapy	82P–0316	September 5, 1990, 55 FR 36578
New Drug and Antibiotic Application Review; Proposed User Charge	84N–0101	August 6, 1985, 50 FR 31726
Proposed Uses of Vinyl Chloride Polymers	84N–0334	February 3, 1986, 51 FR 4177
Unmodified Food Starches and Acid-Modified Starches; Proposed Affirmation of GRAS Status as Direct and Indirect Food Ingredients	84N–0341[1]	April 1, 1985, 50 FR 12821
Use of Acrylonitrile Copolymers	85N–0145	March 8, 1990, 55 FR 8476
Hematology and Pathology Devices; Premarket Approval of the Automated Blood Cell Separator Intended for Routine Collection of Blood and Blood Components	85N–0241	February 19, 1988, 53 FR 5108
New Drugs for Human Use: Proposed Clarification of Requirements for Application Supplements	86N–0077	June 4, 1986, 51 FR 20310
Quality Standard for Foods With No Identity Standards; Bottled Water	86N–0445	September 16, 1988, 53 FR 36063
Pineapple Juice; Proposal to Amend U.S. Standards of Identity and Quality	86P–0338	May 21, 1987, 52 FR 19169
New Animal Drug Regulations	88N–0058	December 17, 1991, 56 FR 65544
Current Good Manufacturing Practices for Blood and Blood Components; Proficiency Testing Requirements	88N–0413	June 6, 1989, 54 FR 24296
Canned Pineapple; Proposal to Amend Standards of Identity and Quality	88P–0224	March 24, 1989, 54 FR 12237
Shellac and Shellac Wax; Proposed Affirmation of GRAS Status With Specific Limitations as Direct Human Food Ingredients	89N–0106	July 26, 1989, 54 FR 31055
Erythromycin Capsules; Proposed Amendment of Dissolution Standard of Erythromycin Capsules	89N–0378[1]	October 26, 1989, 54 FR 43592
Yogurt Products; Frozen Yogurt, Frozen Lowfat Yogurt, and Frozen Nonfat Yogurt; Petitions to Establish Standards of Indentity and to Amend the Existing Standards	89P–0208 and 89P–0444	May 31, 1991, 56 FR 24760
Exemption From Preemption of State and Local Hearing Aid Requirements; Vermont	89P–0314	October 30, 1990, 55 FR 45615
Amend Animal Care Regulations	89P–0320	July 3, 1990, 55 FR 27476
Food Labeling; Declaration of Ingredients; Common or Usual Name Declaration for Protein Hydrolysates and Vegetable Broth in Canned Tuna; "and/or" Labeling for Soft Drinks	90N–361M	January 6, 1993, 58 FR 2950
Use of Aseptic Processing and Terminal Sterilization in the Preparation of Sterile Pharmaceuticals for Human and Veterinary Use	91N–0074	October 11, 1991, 56 FR 51354
Cosmetic Products Containing Certain Hormone Ingredients; Notice of Proposed Rulemaking	91N–0245	September 9, 1993, 58 FR 47611
Substances in Food-Contact Articles in the Household, Food Service Establishments, and Food Dispensing Equipment	91N–0313	April 12, 1974, 39 FR 13285

TABLE 1.—Continued

Title	Docket No.	FR publication date and cite
Drug Listing Compliance Verification Reports	92N–0291	September 2, 1993, 58 FR 46587
Food Labeling; Metric Labeling Requirements	92N–0406	May 21, 1993, 58 FR 29716
Food Labeling, Net Quantity of Contents; Compliance	92P–0441	March 4, 1997, 62 FR 9826
Cardiovascular Devices; Effective Date of Requirement for PMA of Nonroller-Type Cardiopulmonary Bypass Blood Pump	93M–0150	July 6, 1993, 58 FR 36290
Amendment of Performance Standards; Laser Products	93N–0044	March 24, 1999, 64 FR 14180
Quality Standards for Foods With No Identity Standards; Bottled Water	93N–0200	October 6, 1993, 58 FR 52042
Metric Labeling; Quantity of Contents Labeling Requirement for Foods, Human and Animal Drugs, Animal Foods, Cosmetics, and Medical Devices	92N–0406 and 93N–0226	December 21, 1993, 58 FR 67444
Lead in Food and Color Additives and GRAS Ingredients; Request for Data	93N–0348	February 4, 1994, 59 FR 5363
Substances Prohibited From Use in Animal Food or Feed; Specified Offal From Adult Sheep and Goats Prohibited in Ruminant Feed; Scrapie	93N–0467	August 29, 1994, 59 FR 44584
Dental Devices; Effective Date of Requirement for Premarket Approval of Over-the-Counter (OTC) Denture Cushions or Pads and OTC Denture Repair Kits	95N–0034	July 11, 1995, 60 FR 35713
Food Labeling, Nutrient Content Claims and Health Claims; Special Requirements	95N–0103	February 2, 1996, 61 FR 3885
Maltodextrin; Food Chemicals Codex Specifications	95N–0189	September 21, 1995, 60 FR 48939
Beverages: Bottled Water	95N–0203	November 13, 1995, 60 FR 57132
Dental Devices; Effective Date of Requirement for Premarket Approval of Partially Fabricated Denture Kits	95N–0298	November 29, 1995, 60 FR 61232
Yogurt; Low Fat And Non-Fat, Revocation	95P–0250	November 9, 1995, 60 FR 56541
Food Standards; Reinvention of Regulations Needing Revisions; Request for Comments on Certain Existing Regulations	96N–0149	June 12, 1996, 61 FR 29701
Reinvention of Certain Food Additive Regulations	96N–0177	June 12, 1996, 61 FR 29711
Food Labeling; Declaration of Free Glutamate in Food	96N–0244	September 12, 1996, 61 FR 48102
Regulation of Medical Foods	96N–0364	November 29, 1996, 61 FR 60661
Food Labeling: Nutrient Content Claims Pertaining to the Available Fat Content of Food	96N–0421 and 94P–0453/CP1	December 20, 1996, 61 FR 67243
Food Labeling; Serving Sizes; Reference Amounts for Candies	96P–0023 and 96P–0179	January 8, 1998, 63 FR 1078

[1]Denotes documents that were included in the December 1991 withdrawal notice, but were not withdrawn at that time.

II. Submission of Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic 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 found

in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 4/10/03

April 10, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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