investigation, consolidate proceedings before it, and determine the scope and manner of its proceedings;

(b) *Initiation of investigations.* Investigations may be initiated by the Commission on the Commission's own motion, upon request of the President or the Special Representative for Trade Negotiations, upon resolution of the Committee on Ways and Means of the House of Representatives or the Committee on Finance of the Senate, upon resolution of either branch of Congress, or upon application, petition, complaint, or request of private parties, as required or provided for in the pertinent statute, Presidential proclamation, Executive Order, or in this chapter.

[44 FR 76476, Dec. 26, 1979]

[FR Doc. 97–55555 Filed 7–22–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 50

[Docket No. 95N–0340]

RIN 0910–AA54

Revocation of Certain Regulations; General

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking 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.

EFFECTIVE DATE: August 22, 1997.

FOR FURTHER INFORMATION CONTACT:

Regarding the regulations mentioned in this document: Philip L. Chao, Policy Development and Coordination Staff (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

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

SUPPLEMENTARY INFORMATION: On March 4, 1995, President Clinton announced plans for reforming the Federal regulatory system as part of his ''Reinventing Government'' initiative. In his March 4 directive, the President ordered all Federal agencies to conduct a page-by-page review of their regulations and to ''eliminate or revise those that are outdated or otherwise in need of reform.'' In the **Federal Register** of January 25, 1996 (61 FR 2192), FDA issued a proposal to revoke certain obsolete and unnecessary regulations. The proposal represented FDA's continuing effort to implement the President's plan and followed other proposals in previous issues of the **Federal Register** revoking or revising other FDA regulations.

The following is a section-by-section analysis of the regulations that FDA proposed to revoke and any comments or issues associated with those regulations. These regulations are listed numerically as they appear in title 21 of the Code of Federal Regulations (CFR).

I. Section-by-Section Analysis

(1) Section 1.31 *Package size saving* (21 CFR 1.31) addressing economy size packaging. FDA proposed to revoke this provision because it is obsolete, and FDA is not aware of its recent use.

FDA received one comment on this provision, and the comment expressed no objection to revoking this provision. Consequently, § 1.31 is revoked.

(2) Section 1.35 *''Cents-off,'' or other savings representations* (21 CFR 1.35) prohibiting the placement of any printed matter stating or representing by implication that a product is offered for sale at a price that is lower than the ordinary and customary retail price. FDA proposed to revoke this provision because it is obsolete, and FDA is not aware of its recent use.

FDA received one comment on this provision, and the comment expressed no objection to revoking this provision. Consequently, the agency has revoked § 1.35.

(3) Section 2.5 *Imminent hazard to the public health* (21 CFR 2.5) describes the criteria that the Commissioner of Food and Drugs would use in determining whether an imminent hazard exists. FDA issued this regulation in the **Federal Register** of July 1, 1971 (36 FR 12516). FDA proposed to revoke § 2.5 in the **Federal Register** of August 21, 1979 (44 FR 48983), in conjunction with broader rulemaking proceedings that would have established by regulation, among other things, certain criteria for the Secretary of Health and Human Services' (the Secretary) determination of an imminent hazard. FDA later withdrew the 1979 proposed rule on January 20, 1994 (59 FR 3042). However, the principle upon which FDA based its proposed withdrawal of § 2.5 in 1979 is still valid, namely, that it is ''potentially confusing to have criteria for FDA's recommendations to the Secretary separate from the criteria for the Secretary's decision'' (44 FR 48983 at 48985). The criteria used by the Secretary in finding an imminent hazard were established in 1977 in the Secretary's decision declaring phenformin hydrochloride to be an imminent hazard. This decision was upheld in *Forsham* v. *Califano*, 442 F.Supp. 203 (D. D.C. 1977). Consequently, FDA again proposed to revoke § 2.5 because it is potentially confusing and no longer necessary (61 FR 2192).

The agency did not receive any comments on the proposal to revoke § 2.5. However, upon further reflection, FDA has decided to retain § 2.5 because the terms ''imminent hazard'' appear in several provisions of the Federal Food, Drug, and Cosmetic Act (the act) and its implementing regulations (see, e.g., section 402(f)(1)(C) of the act (21 U.S.C. 342(f)(1)(C)) (concerning adulteration of dietary supplements); section 512(e)(1) of the act (21 U.S.C. 360b(e)(1)) concerning withdrawals of approval of animal drugs); section 802(f) of the act (21 U.S.C. 382(f)) (concerning prohibition of exports); 21 CFR 314.153(a)(1) (suspension of approval of abbreviated new drug applications); 21 CFR 804.28(b)(3) (medical device reporting for distributors)). Therefore, to continue providing guidance in interpreting these and other provisions in the act and FDA regulations, the agency is retaining § 2.5.

(4) 21 CFR part 10, subpart C, Electronic Media Coverage of Public Administrative Proceedings; Guideline on Policy and Procedures, described FDA's policy on the presence and operation of electronic recording equipment at public proceedings. The preamble to the proposed rule explained that the subpart ''is a statement of policy and need not be codified. The information is available to those presiding over such proceedings through appropriate agency publications (e.g., Policy and Guidance Handbook for FDA Advisory Committee Members' and from the staff in FDA's Office of Public Affairs'' (61 FR 2192 and 2193).

FDA received one comment arguing against deleting the subpart. The comment explained that ''policy can

change more readily than regulations or guidelines'' so that ''the freedom to electronically cover public meetings is too important to be changed only as a result of internal Agency deliberation * * * if this policy is to be modified, it should be done so only in accordance with standard rule-making procedures, with a public comment period on the specific changes * * *.''

FDA has decided to retain subpart C even though the agency continues to maintain that guidelines and policy statements neither need to be codified in the CFR nor issued through notice and comment rulemaking. FDA is retaining subpart C in its regulations because, on rare occasions, the agency has cited provisions in subpart C to address certain issues, such as whether cameras are allowed at a particular meeting. The fact that subpart C is a regulation, and therefore more binding than a guideline, has also made it easier for interested parties to read and to adhere to FDA's decisions on electronic media at a public meeting.

Furthermore, FDA fully intends to seek public participation in the initiation, development, and issuance of guidance documents and is taking steps to improve its guidance document procedures (see 62 FR 8961, February 27, 1997 (establishing ''good guidance practices'')). Improved guidance document procedures should address the comment's principal concern that the public should have the opportunity to comment on changes to guidance documents.

(5) Section 50.21 *Effective date* (21 CFR 50.21) stated that the informed consent requirements in part 50 ''apply to all human subjects entering a clinical investigation that commences on or after July 27, 1981.'' FDA proposed to revoke this provision because it is no longer necessary. The preamble to the proposed rule explained that FDA is unaware of any continuing clinical investigations that were begun before July 27, 1981, to warrant retaining this provision.

FDA received no comments on this provision and has revoked § 50.21.

(6) 21 CFR part 50, subpart C, Protections Pertaining to Clinical Investigations Involving Prisoners as Subjects, described restrictions on clinical investigations involving prisoners, including special requirements for institutional review boards reviewing clinical investigations involving prisoners. In the **Federal Register** of July 7, 1981 (46 FR 35085), FDA stayed the effective date of the subpart C regulations and never made them effective. Consequently, the January 25, 1996, proposed rule would revoke the subpart C regulations.

FDA received no comments on this subpart and has revoked subpart C of part 50 as well as the definition of ''prisoner'' at § 50.3(j) and renumbered the remaining definitions accordingly.

II. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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 final rule is consistent with the regulatory philosophy and principles set out in the Executive Order. In addition, the rule is not a significant regulatory action as defined in Executive Order 12866.

Unless the agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires the agency to analyze regulatory options that would minimize any significant impact of a rule on small entities. This final rule eliminates certain regulatory provisions that the agency has not used or made effective or that have become obsolete. Consequently, the agency certifies that this final 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.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 50

Human research subjects, Prisoners, Reporting and recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1 and 50 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 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, 403, 502, 505, 512, 602, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 352, 355, 360b, 362, 371); sec. 215 of the Public Health Service Act (42 U.S.C. 216).

§ 1.31 [Removed]

2. Section 1.31 *Package size savings* is removed from subpart B.

§ 1.35 [Removed]

3. Section 1.35 *''Cents-off,'' or other savings representations* is removed from subpart B.

PART 50—PROTECTION OF HUMAN SUBJECTS

4. The authority citation for 21 CFR part 50 continues to read as follows:

Authority: Secs. 201, 406, 408, 409, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 701, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 371, 379e, 381); secs. 215, 301, 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263b–263n).

§ 50.3 [Amended]

5. Section 50.3 *Definitions* is amended by removing paragraph (j), and redesignating paragraphs (k), (l), (m) and (n) as paragraphs (j), (k), (l) and (m), respectively.

§ 50.21 [Removed]

6. Section 50.21 *Effective date* is removed from subpart B.

Subpart C [Removed]

7. Subpart C consisting of §§ 50.40 through 50.48 is removed.

Dated: July 14, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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