approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before January 15, 1997 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.2010 is amended in the table in paragraph (b) by revising the entry for ''2-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]dioxaphosphepin-6-yl]oxy]-*N*, *N*-bis[2-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]dioxaphosphepin-6-yl]oxy]ethyl]ethanamine'' under the heading ''Limitations'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * *	* * * *
2-[[2,4,8,10-Tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]-dioxaphosphepin-6-yl]oxy]-*N*,*N*-bis[2-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]dioxaphosphepin-6-yl]oxy]ethyl]ethanamine (CAS Reg. No. 80410–33–9).	For use only at levels not to exceed 0.075 percent by weight of olefin copolymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, or 2.3: *Provided*, That the density of the olefin polymers complying with items 2.1, 2.2, or 2.3 is not less than 0.94 gram per cubic centimeter: *And further provided*, That the finished polymers contact food only of Types I, II, IV–B, VI–A, VI–B, VII–B, and VIII described in Table 1, of § 176.170(c) of this chapter, under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter and food only of Types III, IV–A, V, VI–C, VII–A, and IX described in Table 1 of § 176.170(c) of this chapter, under conditions of use C through G described in Table 2 of § 176.170(c) of this chapter.
* * *	* * * *

Dated: November 27, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–31860 Filed 12–13–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 355

[Docket No. 80N–0042]

RIN 0910–AA01

Anticaries Drug Products for Over-the-Counter Human Use; Partial Stay of Final Rule; Enforcement Policy

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial stay of regulation; enforcement policy.

SUMMARY: The Food and Drug Administration (FDA) is staying part of a final rule that established conditions under which over-the-counter (OTC) anticaries drug products (products that aid in the prevention of dental cavities) are generally recognized as safe and effective and not misbranded (60 FR 52474, October 6, 1995). This final rule stays the testing procedures for fluoride dentifrice drug products to provide manufacturers an additional 12 months to comply with these testing requirements. This action is being taken in response to a citizen petition requesting this stay and is part of the

ongoing review of OTC drug products conducted by FDA.

DATES: This partial stay for § 355.70 (21 CFR 355.70), added by 60 FR 52474 at 52510, is effective September 23, 1996, and stays § 355.70(a) until October 7, 1997.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–105), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2304.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 6, 1995 (60 FR 52474), FDA issued a final monograph for OTC anticaries drug products (21 CFR part 355) establishing conditions under which the drug products that are subject to that monograph will be generally recognized as safe and effective and not misbranded. The final monograph established in § 355.70 testing procedures for fluoride dentifrice drug products. The testing procedures require the product to meet the biological test requirements for animal caries reduction and one of the following tests: Enamel solubility reduction or fluoride enamel uptake. The effective date of the monograph was October 7, 1996.

On April 17, 1996, the Joint Oral Task Group of the Nonprescription Drug Manufacturers Association (NDMA) and the Cosmetic, Toiletry and Fragrance Association (CTFA) (the Task Group) submitted a citizen petition (Ref. 1) requesting that the agency stay the effective date for the biological testing requirements for OTC fluoride dentifrice drug products from October 7, 1996, to October 7, 1997. The petition contended that manufacturers needed additional time to comply with the required biological testing requirements and to further implement the Industry/U.S. Pharmacopeia (USP) Reference Standard Program.

The petition stated that at least 34 fluoride-containing dentifrice products would not be in compliance with the biological testing requirements of the final monograph by the effective date of October 7, 1996. The petition explained that there are only four testing laboratories considered fully experienced to perform the required biological testing and that these laboratories can only conduct a total of 32 tests per year. The petition estimated that it would take about 8 months to validate additional laboratories to do the animal caries reduction test. The petition argued that additional time was needed because the animal caries reduction test was an optional test in the tentative final monograph but a required test in the final monograph, and industry did not become aware of this change until the final monograph was published and was not prepared to meet this requirement at that time. The petition contended that, because at least 67 products must be tested, there is insufficient time to complete the needed testing by October 7, 1996, and that a 12-month extension until October 7, 1997, would allow manufacturers sufficient time to perform the required tests.

The petition noted two other problems that precluded compliance with the October 7, 1996, effective date: (1) Several current USP reference standards have not been retested to confirm their quality standards, and (2) a lack or limited number of available USP reference standards to fulfill the unanticipated requirements in the final monograph for animal caries reduction testing.

Following a meeting (Ref. 2) and correspondence (Ref. 3) from FDA, the Task Group provided the agency industry's formalized procedures for handling USP dentifrice reference standards (Ref. 4), entitled ''Protocol for Submission & Maintenance of USP Fluoride Dentifrice Reference Standards.'' The Task Group indicated that resupply and retesting of currently available USP fluoride dentifrice reference standards would be completed by July 1996, and that the two new USP fluoride dentifrice reference standards (i.e., 1,500 parts per million sodium monofluorophosphate dentifrice and sodium fluoride dentifrice in a powdered dosage form) would be available by the beginning of June 1996. The agency has verified that this retesting has been completed and that the new reference standards are currently available (Ref. 5).

On September 5, 1996 (Ref. 6), the Task Group provided the results of a biological testing implementation survey in support of its request for a 1-year stay of the effective date of this part of the final monograph. The Task Group pointed out that 37 dentifrice products remain to be tested and it usually takes 3 to 4 months to complete the test and receive a final report. The Task Group stated that all testing was currently projected to begin by February 1997 but that less than a 1-year delay would not allow for unforeseen circumstances during testing and during the administration of the Industry/USP Reference Standard Program to supply the testing standards.

II. The Agency's Response to the Petition

The agency acknowledges that requiring the animal caries reduction test was a new requirement of the final monograph. In a letter to NDMA dated September 23, 1996 (Ref. 7), FDA agreed to stay the effective date of the testing procedures for fluoride dentifrice drug products for 12 months. FDA reviewed the biological testing implementation survey (Ref. 6), which indicated that approximately 92 percent of the dentifrice products that require testing should be tested by March 30, 1997, and that testing of the remaining products should be completed by June 30, 1997. The agency believes that it would be reasonable to provide an additional 3 months to allow for unforeseen circumstances during the conduct of this testing. Therefore, based on the survey data, the agency is staying the testing procedures for fluoride dentifrice drug products in § 355.70(a) of the final monograph for OTC anticaries drug products for 12 months until October 7, 1997. However, based on the survey and the petitioner's assurances, the agency does not anticipate granting any additional time beyond October 7, 1997, for manufacturers to complete the required biological testing for existing OTC anticaries drug products.

Publication of this document constitutes final action on this change under the Administrative Procedure Act (5 U.S.C. 553). This final rule institutes a change that is nonsubstantive in nature. FDA finds that notice and comment procedures are unnecessary and not in the public interest (5 U.S.C. 533(b) and (d)). The agency believes that staying § 355.70(a) for 12 months will provide sufficient time for industry to comply with the testing procedures for fluoride dentifrice drug products included in the final monograph.

III. References

The following references are on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

(1) Comment No. CP6, Docket No. 80N–0042, Dockets Management Branch.

(2) Comment No. MM7, Docket No. 80N–0042, Dockets Management Branch.

(3) Comment No. LET29, Docket No. 80N–0042, Dockets Management Branch.

(4) Comment No. PR1, Docket No. 80N–0042, Dockets Management Branch.

(5) Comment No. C104, Docket No. 80N–0042, Dockets Management Branch.

(6) Comment No. EXT9, Docket No. 80N–0042, Dockets Management Branch.

(7) Comment No. LET36, Docket No. 80N–0042, Dockets Management Branch.

IV. 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 identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of a rule on small entities. This final rule stays the effective date of testing requirements that became effective on October 7, 1996, but which will not be required now until October 7, 1997. Thus, this final rule will not impose a significant economic burden on affected entities. Therefore, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner of Food and Drugs certifies that this final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) 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 in 21 CFR Part 355

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 355 is amended as follows:

PART 355—ANTICARIES DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 355 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).

§ 355.70 [Partial stay]

2. In § 355.70 *Testing procedures for fluoride dentifrice drug products*, paragraph (a) is stayed until October 7, 1997.

Dated: December 5, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–31575 Filed 12–13–96; 8:45 am]

BILLING CODE 4160–01–F

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 210

Donation of Dairy Products To Assist Needy Persons Overseas (Section 416 Foreign Donation Program)

AGENCY: Agency for International Development, IDCA.

ACTION: Final rule.

SUMMARY: The authority for donations of dairy products to assist the needy overseas has been removed from the Agency for International Development, thereby making these regulations obsolete. These donation regulations are being removed.

EFFECTIVE DATE: December 16, 1996.

FOR FURTHER INFORMATION CONTACT: James Dempsey, Director, Office of Planning and Program Evaluation (AID/BHR/PPE), Bureau for Humanitarian Response, USAID, (703) 351–0102.

SUPPLEMENTARY INFORMATION: 22 CFR part 210 is obsolete. New regulations are being issued by the U.S. Department of Agriculture. The 22 CFR, part 210 rule is not a major rule for purposes of Executive Order 12291 of February 17, 1991. As required by the Regulatory Flexibility Act, it is hereby certified that this rule will not have a significant impact on small business entities.

List of Subjects in 22 CFR Part 210

Agricultural commodities, Foreign assistance.

PART 210—[REMOVED]

For the reasons set forth above, 22 CFR part 210 is removed.

Authority: 22 U.S.C. 2381(a).

Dated: November 22, 1996.

James Dempsey,

Director, AID/BHR/PPE.

[FR Doc. 96–30990 Filed 12–13–96; 8:45 am]

BILLING CODE 6116–01–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 8690]

RIN–1545–AS94

Deductibility, Substantiation, and Disclosure of Certain Charitable Contributions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance regarding the allowance of certain charitable contribution deductions, the substantiation requirements for charitable contributions of $250 or more, and the disclosure requirements for quid pro quo contributions in excess of $75. The regulations will affect organizations described in section 170(c) and individuals and entities that make payments to these organizations.

EFFECTIVE DATE: These regulations are effective December 16, 1996.

FOR FURTHER INFORMATION CONTACT: Jefferson K. Fox of the Office of Assistant Chief Counsel (Income Tax and Accounting) at 202–622–4930 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–1464. Responses to this collection of information are required for charitable contribution deductions under section 170.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The estimated annual burden per recordkeeper varies from three minutes to one hour, depending on individual circumstances, with an estimated average of six minutes.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, PC:FP, Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and