Dated: June 9, 2000.

Kenneth S. Apfel,

Commissioner of Social Security.

PART 404–FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950—)

Accordingly, the interim final rules amending 20 CFR Part 404 published at 64 FR 57774 on October 27, 1999, are adopted as final without change.

[FR Doc. 00–15644 Filed 6–20–00; 8:45 am]

BILLING CODE 4191–02–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 99F–1421]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its food additive regulations that provide for the safe use of tetradecanoic acid, lithium salt as a stabilizer for polypropylene and certain polypropylene copolymers intended for use in contact with food. When the regulation was last amended, the regulation published with some errors. This document corrects those errors.

DATES: This rule is effective June 21, 2000.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: FDA has discovered that two errors have become incorporated into the agency's current food additive regulations. In an amendment to 21 CFR 178.2010, published in the **Federal Register** of December 27, 1999 (64 FR 72273), there were errors regarding the food type VI–B. This document corrects those errors. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment is nonsubstantive.

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: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b) under the heading ''Limitations'' by revising the entry for ''Tetradecanoic acid, lithium salt'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * * * * * *	
Tetradecanoic acid, lithium salt (CAS Reg. No. 20336–96–3)	For use only at levels not to exceed 0.15 percent by weight of polypropylene and polypropylene copolymers complying with § 177.1520(c) of this chapter, items 1.1a, 1.1b, 3.1a, 3.1b, 3.1c, 3.2a, and 3.2b. The finished polymers may only be used in contact with food of Types I, II, IV–B, VI–B, VII–B, and VIII as described in table 1 of § 176.170(c) of this chapter under conditions of use B through H as described in table 2 of § 176.170(c) of this chapter, and with food of Types III, IV–A, V, VI–A, VI–C, VII–A, and IX described in table 1 of § 176.170(c) of this chapter under conditions of use C through G as described in table 2 of § 176.170(c) of this chapter.
* * * * * * *	

Dated: June 7, 2000.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–15561 Filed 6–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 349

[Docket No. 98N–0002]

RIN 0910–AA01

Ophthalmic Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the monograph for over-the-counter (OTC) ophthalmic drug products (the regulation that establishes conditions under which these drug products are generally recognized as safe and effective and not misbranded). The amendment adds a new warning and revises an existing warning for ophthalmic vasoconstrictor drug products. These products contain the ingredients ephedrine hydrochloride, naphazoline hydrochloride, phenylephrine hydrochloride, or

tetrahydrozoline hydrochloride and are used to relieve redness of the eye due to minor eye irritations. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES: *Effective Date:* This rule is effective May 16, 2002.

Compliance Date: The compliance date for products with annual sales less than $25,000 is May 16, 2003. The compliance date for all other OTC drug products is May 16, 2002.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2307.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 4, 1988 (53 FR 7076), FDA published a final monograph for OTC ophthalmic drug products in part 349 (21 CFR part 349). That monograph includes four ophthalmic vasoconstrictor active ingredients in § 349.18. Section 349.3(i) defines an ophthalmic vasoconstrictor as ''A pharmacologic agent which, when applied topically to the mucous membranes of the eye, causes transient constriction of conjunctival blood vessels.'' Section 349.75(a) and (b) provide that these products are labeled with the statement of identity ''redness reliever'' or ''vasoconstrictor (redness reliever)'' ''eye'' or ''ophthalmic'' [dosage form, e.g., ''drops''] and with the indication for use ''Relieves redness of the eye due to minor eye irritations.'' Section 349.75(c)(2) requires these products to bear the warning statement: ''If you have glaucoma, do not use this product except under the advice and supervision of a doctor.''

In the **Federal Register** of February 23, 1998 (63 FR 8888), the agency published a proposed amendment of the monograph for OTC ophthalmic drug products to revise this glaucoma warning by adding the words ''narrow angle'' before the word ''glaucoma'' and to add a new warning for ophthalmic vasoconstrictor drug products that states: ''Pupils may become dilated (enlarged).'' The agency also invited comment on whether to add the words ''This is temporary and not serious'' as a required or optional statement after the proposed new warning. The agency explained that these proposed labeling revisions were based primarily on the labeling approved in recent years for three new drug applications (NDA's) for ophthalmic drug products containing pheniramine maleate and naphazoline hydrochloride and adverse drug experience (ADE) reports submitted to those NDA's.

Interested persons were invited to submit comments on the proposal and on the agency's economic impact determination by May 26, 1998. In response to the proposed monograph amendment, one trade association of OTC drug manufacturers submitted a comment, a copy of which is on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

The agency has considered the comment in proceeding with this final rule. A summary of the comment with FDA's response follows.

II. Summary of the Comment Received

The comment supported the agency's rationale for the proposed warning regarding narrow angle glaucoma, stating that the clarification of the warning was clinically rational and in the best interest of the public health. The agency is including this revision in this final rule.

The comment disagreed with the warning statement about pupils becoming dilated, stating that the warning is not appropriate for single ingredient ophthalmic vasoconstrictor drug products. The comment noted that the agency's proposal is based on ADE reports from combination antihistamine-vasoconstrictor ophthalmic products, while pupil dilation reports for single ingredient vasoconstrictor ophthalmic products are rare, given the high incidence of exposure to these products. The comment provided comparative figures to show that the ADE profile is different for the two types of products, concluding that the numbers do not justify a new warning on single ingredient products. The comment requested the agency to withdraw its proposal for this pupil dilation warning for single ingredient, monographed ophthalmic vasoconstrictor drug products.

The agency does not accept the comment's suggestion. Both the Advisory Review Panel on OTC Ophthalmic Drug Products (45 FR 30002 at 30033, May 6, 1980) and standard text books (Ref. 1) state that pupil dilation is a known pharmacologic effect of sympathomimetic drugs such as these ophthalmic vasoconstrictors. In both the combination (antihistamine-vasoconstrictor) and the single ingredient (vasoconstrictor) products, the vasoconstrictor ingredient is considered the cause of the pupil dilation. The difference in ADE reports between single ingredient and combination products may be because the combination products are marketed under NDA's, which have ADE reporting requirements. The agency stated in the proposal and concludes here that it would be beneficial and informative to consumers who use these products (single ingredient or combination) to know that their pupils may become enlarged temporarily. Therefore, the agency is including a warning in this final rule.

The comment contended that the pupil dilation warning appears to have little practical relationship to the goal of reducing ADE reports to the agency. The comment added that the potential for pupil dilation is not serious and, thus, questioned the need to mention the event in product labeling. The comment did not offer any alternative language for the warning.

The agency believes that the comment misunderstood the agency's objective, which was not to reduce the number of ADE reports to the agency. Rather, the agency's objective in proposing to add the warning was to inform consumers about this effect of the drug and to improve their self-use of these products. The agency concludes that information in the product's labeling about pupil dilation will enable many consumers to continue using these products and not discontinue use after one or two instillations because they do not know to expect possible temporary pupil enlargement to occur. The agency has decided to combine the second statement discussed in the proposal (''This is temporary and not serious.'') with the first statement in a shortened version in this final rule. The warning, in the new OTC drug labeling format, now reads: ''When using this product [in bold type] pupils may become enlarged temporarily.''

III. The Agency's Final Conclusions

The agency concludes that adding the following new warning in § 349.75(c)(5) would benefit consumers who use an OTC ophthalmic drug product containing a vasoconstrictor active ingredient: ''When using this product [in bold type] pupils may become enlarged temporarily.'' The agency is amending § 349.75(c)(2) to add the words ''narrow angle'' before ''glaucoma.'' The warning now reads, in the new OTC drug labeling format: ''Ask a doctor before use if you have [in bold type] narrow angle glaucoma.''

IV. Reference

1. ''Drug Facts and Comparisons,'' Facts and Comparisons, St. Louis, p. 483b, 1998 ed.

V. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*). 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). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities.

Title II of the Unfunded Mandates Reform Act requires that agencies prepare a written statement and economic analysis before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

The agency concludes that this final rule is consistent with the principles set out in the Executive Order and in these two statutes. 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. This section constitutes the agency's final regulatory flexibility analysis under the Regulatory Flexibility Act. Further, because this final rule makes no mandates on government entities and will result in expenditures less than $100 million in any one year, FDA need not prepare additional analyses under the Unfunded Mandates Reform Act.

The purpose of this final rule is to add a new warning and to revise an existing warning for OTC ophthalmic vasoconstrictor drug products. These warning statements should improve consumers' self use of these drug products and enable some consumers with glaucoma to self medicate when necessary. The agency stated in the proposal that manufacturers of these products will incur costs to relabel their products to include the new labeling information (63 FR 8888 at 8889). The agency indicated that relabeling costs of the type required by this rule generally average about $2,000 to $3,000 per stock keeping unit (SKU) (individual products, packages, and sizes). In determining this cost, the agency did not believe that manufacturers would need to increase the package size to add the few additional words in the new warning. Almost all of these products are marketed in an outer carton which should have adequate space for the additional information. The agency noted that 50 manufacturers, most of which are small manufacturers, together produce about 100 SKU's of OTC ophthalmic vasoconstrictor drug products marketed under the monograph. There may be a few additional small manufacturers or products in the marketplace that are not identified in the sources FDA reviewed. Assuming that there are about 100 affected OTC SKU's in the marketplace, FDA estimated that the rule would impose total one-time compliance costs on industry for relabeling of about $200,000 to $300,000. The agency did not receive any comments on these estimates.

The agency believes the actual cost could be lower for several reasons. First, most of the label changes will be made by private label small manufacturers that tend to use simpler and less expensive labeling. However, the final rule will not require any new reporting and recordkeeping activities. Therefore, no additional professional skills are needed. Second, the agency has made the compliance dates for this final rule the same as the dates for these monographed products to be in compliance with the new standardized format and standardized content requirements for the labeling of OTC drug products (21 CFR 201.66), which are now May 16, 2002 (and May 16, 2003, for products with annual sales less than $25,000). Thus, all required labeling changes can be made at the same time, thereby reducing the labeling cost of this final rule.

The agency considered but rejected several labeling alternatives: (1) A shorter or longer implementation period, and (2) an exemption from coverage for small entities. While the agency believes that consumers would benefit from having this new labeling in place as soon as possible, the agency also acknowledges that coordination of this labeling change with implementation of the new OTC ''Drug Facts'' labeling may significantly reduce the costs of this final rule. Both a shorter and a longer time period for this rule may cost more if firms would have to undertake two successive labeling revisions. In addition, a longer time period would unnecessarily delay the benefit of the new labeling to consumers who self-medicate with these OTC ophthalmic vasoconstrictor drug products. The agency rejected an exemption for small entities because the new labeling information is also needed by consumers who purchase products marketed by those entities. However, the agency is providing a compliance date of May 16, 2003 for products with annual sales less than $25,000.

This analysis shows that the agency has undertaken important steps to reduce the burden to small entities. Thus, this economic analysis, together with other relevant sections of this document, serves as the agency's final regulatory flexibility analysis, as required under the Regulatory Flexibility Act.

VI. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this final rule are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the warning statements are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VII. Environmental Impact

The agency has determined under 21 CFR 25.31(a) 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 349

Labeling, Ophthalmic goods and services, 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 349 is amended as follows:

PART 349—OPHTHALMIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 349 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 349.75 is amended by revising paragraph (c)(2) and by adding paragraph (c)(5) to read as follows:

§ 349.75 Labeling of ophthalmic vasoconstrictor drug products.

* * * * *

(c) * * *

(2) ''Ask a doctor before use if you have [in bold type] narrow angle glaucoma.''

* * * * *

(5) ''When using this product [in bold type] pupils may become enlarged temporarily.''

* * * * *

Dated: June 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–15631 Filed 6–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1952

State Plans: Coverage of the United States Postal Service and Other Coverage Issues—Changes to Level of Federal Enforcement for Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, the Virgin Islands, Washington and Wyoming; Correction

AGENCY: Occupational Safety and Health Administration (OSHA), U.S. Department of Labor.

ACTION: Final rule; correction.

SUMMARY: The Occupational Safety and Health Administration published in the **Federal Register** on June 9, 2000 (65 FR 36617), a document amending its regulations on State Plans to reflect Federal coverage of the United States Postal Service and other coverage issues. In subpart Q, Kentucky, § 1952.236, where the plan may be inspected, was inadvertently designated as § 1952.96. This document corrects that designation.

EFFECTIVE DATE : June 9, 2000.

FOR FURTHER INFORMATION CONTACT: Bonnie Friedman, Director, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, U. S. Department of Labor, Room N3637, 200 Constitution Avenue, NW., Washington, DC 20210, (202) 693–1999.

SUPPLEMENTARY INFORMATION:

Correction of Publication

In the final rule (FR Doc. 00–14150) published in the **Federal Register** on June 9, 2000 (65 FR 36617), make the following correction:

PART 1952—[CORRECTED]

§ 1952.236 [Corrected]

On page 36625, in the first column, following amendatory instruction 31, correctly designate § 1952.96 as § 1952.236.

Authority: This document was prepared under the direction of Charles N. Jeffress, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, D.C. the 14th day of June, 2000.

Charles N. Jeffress,

Assistant Secretary.

[FR Doc. 00–15558 Filed 6–20–00; 8:45 am]

BILLING CODE 4510–26–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: Base (1% annual chance) flood elevations and modified base flood elevations are made final for the communities listed below. The base flood elevations and modified base flood elevations are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

EFFECTIVE DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing base flood elevations and modified base flood elevations for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated on the table below.

ADDRESSES: The final base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Matthew B. Miller, P.E., Chief, Hazards Study Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646–3461.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA or Agency) makes final determinations listed below of base flood elevations and modified base flood elevations for each community listed. The proposed base flood elevations and proposed modified base flood elevations were published in newspapers of local circulation and an opportunity for the community or individuals to appeal the proposed determinations to or through the community was provided for a period of ninety (90) days. The proposed base flood elevations and proposed modified base flood elevations were also published in the **Federal Register**.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67.

The Agency has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and Flood Insurance Rate Map available at the address cited below for each community.

The base flood elevations and modified base flood elevations are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Associate Director, Mitigation Directorate, certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because final or modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the National Flood Insurance Program. No regulatory flexibility analysis has been prepared.

Regulatory Classification

This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.