To prevent simultaneous loss of heating to both pitot probes, which could result in incorrect airspeed indications to both the primary and secondary airspeed indication systems, and consequent reduced controllability of the airplane, accomplish the following:

(a) Within 6 months after the effective date of this AD, modify the airplane wiring to separate the electrical inputs sent by the engine interface units (EIU's) to probe heat computers 1 and 3 in accordance with Airbus Service Bulletin A320–30–1036, dated May 9, 1997.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in French airworthiness directive 97–203–102B, dated August 27, 1997.

Issued in Renton, Washington, on February 13, 1998.

Stewart R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–4410 Filed 2–20–98; 8:45 am]

BILLING CODE 4910–13–U

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; Proposed Amendment of Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the final monograph for over-the-counter (OTC) ophthalmic drug products. 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 they are used to relieve redness of the eye due to minor eye irritations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit written comments by May 26, 1998; written comments on the agency's economic impact determination by May 26, 1998. FDA is proposing that any final rule that may issue based on this proposal become effective 12 months after its date of publication in the **Federal Register**.

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

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 included 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.'' Paragraphs (a) and (b) of § 349.75 provide that these products are labeled with the statement of identity ''redness reliever'' or ''vasoconstrictor (redness reliever)'' ''eye'' or ''ophthalmic'' ''insert (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.''

II. Recent Developments

In the last 3 years, FDA has approved three new drug applications (NDA's) (Ref. 1) for ophthalmic drug products containing pheniramine maleate and naphazoline hydrochloride. These products are used for eye allergy relief to relieve itching and redness of the eye due to pollen, ragweed, grass, animal hair, and dander. These products are not covered by the OTC ophthalmic drug products monograph because the ingredient pheniramine maleate is not included in that monograph.

The agency has received more than 400 adverse drug experience (ADE) reports involving these three products (Ref. 1) in which consumers have reported pupil dilatation (enlarged pupils) after using the eye drops (Ref. 2). Because of the vasoconstrictor action of naphazoline hydrochloride (and the other active ingredients included in § 349.18), pupil dilatation is a known pharmacologic effect of these drugs. The Advisory Review Panel on OTC Ophthalmic Drug Products (the Panel), in its report (May 6, 1980, 45 FR 30002 at 30033), stated that, even at the low concentrations used in OTC drug products, vasoconstrictors occasionally may cause some dilation of the pupil, especially in people who wear contact lens, whose cornea is abraded, or who have lightly colored irides. However, the Panel did not recommend any labeling warning based on this pharmacologic effect of these drugs. The agency also did not include a labeling warning in the past because the enlargement of the pupil(s) is not clinically significant (usually persists for 1 to 4 hours) and does not affect pupil reactivity. As a result, the agency did not mention this pharmacologic side effect in product labeling. Thus, OTC ophthalmic drug products marketed under the monograph or under NDA's do not contain this type of information in their labeling.

The more than 400 ADE reports that have been received have caused the agency to rethink its position on including information about pupil enlargement in the labeling of these OTC vasoconstrictor drug products. The agency now believes that it would be beneficial and informative to consumers to inform them that their pupils may become dilated (enlarged). The agency believes this information in product labeling will reduce the number of ADE reports and will enable consumers to continue using these products and not discontinue use after one or two instillations because they do not expect this pupil enlargement to occur. Accordingly, the agency is proposing to add the following warning in new § 349.75(c)(5) to state: ''Pupils may become dilated (enlarged).''

The agency recognizes that space on OTC ophthalmic drug product labeling is limited, but it considers these additional five words worthwhile because of the number of consumers who have reported this pupil

enlargement as a problem. The agency questions whether it would be additionally beneficial to add several more words, i.e., ''This is temporary and not serious,'' after the first statement so that consumers will not be alarmed if this pupil enlargement occurs and will not discontinue use of the product for this reason. These additional words could be required or optional, if the manufacturer wishes to include them. The agency invites specific comment on the wording of both statements, and the desirability of including the second statement (even if optional).

The Panel also noted that the dilation of the pupil caused by the ophthalmic vasoconstrictor drug may in turn trigger an attack of narrow-angle glaucoma in a susceptible individual (45 FR 30002 at 30033). The Panel recommended the following glaucoma warning for ophthalmic vasoconstrictors: ''If you have glaucoma, do not use this product except under the advice and supervision of a physician.'' (See 45 FR 30002 at 30033.) The agency included this warning in § 349.75(c)(2) of the final monograph for OTC ophthalmic drug products (with the word ''physician'' changed to ''doctor'').

In the three NDA's for the pheniramine maleate-naphazoline hydrochloride eye drop products approved in the last several years, the agency has changed the glaucoma warning to state: ''Do not use this product if you have * * * narrow angle glaucoma unless directed by a physician.'' This was done because the potential risk only applies to people with narrow angle glaucoma, a condition where it is not desirable to use a drug of this type that could cause mid-dilation of the pupil. The agency believes that a number of physicians inform their patients what type of glaucoma they have. Further, it is beneficial for consumers to know this information, and the agency encourages consumers to ask their physician in order to be fully informed and knowledgeable.

III. The Agency's Tentative Conclusions and Proposal

The agency is proposing to add the following new warning in § 349.75(c)(5) to state: ''Pupils may become dilated (enlarged).'' The agency invites comment whether to expand this warning to also state: ''This is temporary and not serious.'' This second statement could be a required or optional statement (because of the limited space available in ophthalmic drug product labeling), added if the manufacturer desires.

The agency is proposing to amend § 349.75(c)(2) to add the words ''narrow angle'' before ''glaucoma.'' The warning would then read: ''If you have narrow angle glaucoma, do not use this product except under the advice and supervision of a doctor.''

The agency is proposing that any final rule that may issue based on this proposal become effective 12 months after its date of publication in the **Federal Register**. The agency considers this new labeling an improvement to the current labeling of OTC ophthalmic vasoconstrictor drug products, but it recognizes that existing products have used the current monograph labeling for over 9 years. Therefore, to reduce relabeling costs for manufacturers of these specific products, the agency might consider an 18-month effective date for any final rule that may issue based on this proposal. This longer effective date would enable manufacturers to use up existing labeling and implement the new labeling in the normal course of reordering labeling for these products. The agency invites specific comment on this extended effective date.

IV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Approved labeling from NDA's 20–065, 20–226, and 20–485.

2. Center for Drug Evaluation and Research, FDA, ''Adverse Drug Experience Report for OTC Ophthalmic Drug Products Containing Pheniramine Maleate and Naphazoline Hydrochloride, May 29, 1997.

V. Analysis of Impacts

FDA has examined the impacts of this proposed 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). 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 (2 U.S.C. 1501 *et seq.*) 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 believes that this proposed rule is consistent with the principles set out in the Executive Order and in these two statutes. The purpose of this proposed 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.

Manufacturers of these products will incur costs to relabel their products to include the new labeling information. The agency has been informed that relabeling costs of the type required by this proposed rule generally average about $2,000 to $3,000 per stock keeping unit (SKU) (individual products, packages, and sizes). The agency is aware of 50 manufacturers that 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, total one-time costs of relabeling would be $200,000 to $300,000. The agency believes the actual cost could be lower for several reasons. Most of the label changes will be made by private label manufacturers that tend to use simpler and less expensive labeling. In addition, the agency is considering and inviting public comment on an 18-month effective date for the final rule, rather than the standard 12-month effective date. This extended effective date may allow the new labeling to be implemented concurrently with the general labeling changes that may be required by the new OTC drug labeling format. (See the **Federal Register** of February 27, 1997, 62 FR 9024.) The agency believes that these actions provide substantial flexibility and reductions in cost for small entities.

The agency considered but rejected several labeling alternatives, such as: (1) A shorter implementation period, and (2) an exemption from coverage for small entities. While the agency would like to have this new labeling in place as soon as possible, it considers a period less than 1 year difficult for manufacturers to implement and not critical in this situation. The agency

does not consider an exemption for small entities appropriate because consumers who use these manufacturers' products would not have the most recent information for the safe and effective use of these OTC ophthalmic vasoconstrictor drug products.

This analysis shows that this proposed rule is not economically significant under Executive Order 12866 and that the agency has undertaken important steps to reduce the burden to small entities. Nevertheless, some entities may incur some impacts, especially private label manufacturers that provide labeling for a number of the affected products. Thus, this economic analysis, together with other relevant sections of this document, serves as the agency's initial regulatory flexibility analysis, as required under the Regulatory Flexibility Act. Finally, this analysis shows that the Unfunded Mandates Act does not apply to the proposed rule because it would not 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.

VI. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements proposed in this document 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 proposed 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 25.30(h) that this action is of a type that is categorically excluded from the preparation of an environmental assessment because these actions, as a class, will not result in the production or distribution of any substance and therefore will not result in the production of any substance into the environment.

VIII. Request for Comments

Interested persons may, on or before May 26, 1998, submit written comments on the proposed regulation to the Dockets Management Branch (address above). Written comments on the agency's economic impact determination may be submitted on or before May 26, 1998. Three copies of all 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 and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

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, it is proposed that 21 CFR part 349 be 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 adding paragraph (c)(5) to read as follows:

§ 349.75 Labeling of ophthalmic vasoconstrictor drug products.

* * * * *

(c) * * *

(2) ''If you have narrow angle glaucoma, do not use this product except under the advice and supervision of a doctor.''

* * * * *

(5) ''Pupils may become dilated (enlarged).''

* * * * *

Dated: January 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–4531 Filed 2–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[REG–105162–97]

RIN 1545–AV41

Treatment of Changes in Elective Entity Classification; Hearing Cancellation

AGENCY: Internal Revenue Service, Treasury.

ACTION: Cancellation of notice of public hearing on proposed regulations.

SUMMARY: This document provides notice of cancellation of a public hearing on proposed regulations regarding the classification of entities for federal tax purposes.

DATES: The public hearing originally scheduled for Tuesday, February 24, 1998, beginning at 10:00 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Lanita Van Dyke of the Regulations Unit, Assistant Chief Counsel (Corporate), (202) 622–7190, (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed regulations under section 7701 of the Internal Revenue Code. A notice of proposed rulemaking and notice of public hearing appearing in the **Federal Register** on Tuesday, October 28, 1997 (62 FR 55768), announced that the public hearing on proposed regulations under section 7701 of the Internal Revenue Code would be held on Tuesday, February 24, 1998, beginning at 10:00 a.m., in room 2615, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, D.C.

The public hearing scheduled for Tuesday, February 24, 1998, is cancelled.

Cynthia E. Grigsby,

Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 98–4383 Filed 2–20–98; 8:45 am]

BILLING CODE 4830–01–U

NATIONAL LABOR RELATIONS BOARD

29 CFR Part 103

Rules Regarding Standardized Remedial Provisions in Board Unfair Labor Practice Decisions and the Appropriateness of Single Location Bargaining Units in Representation Cases

AGENCY: National Labor Relations Board.

ACTION: Withdrawal of proposed rulemakings.

SUMMARY: The NLRB is indefinitely withdrawing from active consideration two rulemaking proceedings: (1) The Notice of Proposed Rulemaking issued on March 5, 1992 entitled Codification of Standardized Remedial Provisions in Board Decisions Regarding Offers of Reinstatement, Make-Whole Remedies, Computation of Interest, and Posting of Notices (57 FR 7897); and (2) the Advanced Notice of Proposed Rulemaking and Notice of Proposed