REVISIONS TO IFR ALTITUDES AND CHANGEOVER POINTS—Continued

[Amendment 440 Effective Date March/20/2003]

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[FR Doc. 03–3970 Filed 2–12–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 349

[Docket No. 03N–0008]

RIN 0910–AA01

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation that established conditions under which over-the-counter (OTC) ophthalmic drug products are generally recognized as safe and effective and not misbranded. This amendment clarifies the active ingredient in OTC eyewash drug products and the labeling of the active ingredient and its purpose. This final rule is part of FDA's ongoing review of OTC drug products.

DATES: *Effective Date*: This rule is effective March 21, 2003.

Compliance Dates: The compliance dates are either February 21, 2005, or the date of the first major labeling revision after the effective date of March 21, 2003.

Comment Dates: Submit written or electronic comments by April 21, 2003.

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*.

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 issued a final monograph for OTC ophthalmic drug products (part 349 (21 CFR part 349)). Section 349.20 of that monograph states that eyewashes contain water, tonicity agents to establish isotonicity with tears, agents for establishing pH and buffering to achieve the same pH as tears, and a suitable preservative agent.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA issued a final rule establishing standardized format and content requirements for the labeling of OTC drug products (§ 201.66 (21 CFR 201.66)). Section 201.66(c)(2) requires the labeling to state the established name of each active ingredient and the quantity in each dosage unit stated in the directions for use. Section 201.66(c)(3) requires the labeling to state the purpose of each active ingredient, which is the general pharmacological category or the principal intended action of the drug. When an OTC drug monograph contains a statement of identity, the pharmacological action described in the statement of identity shall also be stated as the purpose of the active ingredient. Section 201.66(c)(8) requires a listing of the established name of each inactive ingredient.

II. Clarification

Manufacturers of OTC eyewash drug products have requested clarification on how to list the active and inactive ingredients for these products to comply with § 201.66(c)(2) and (c)(8). The agency has determined that the active ingredient of these eyewash drug products is water, and that tonicity, hydrogen-ion concentration (pH) and buffering, and preservative agents should be listed as inactive ingredients. Based on the statement of identity in § 349.78(a), the agency has also determined that the purpose of the water may be stated as either ''eyewash'' or ''eye irrigation.''

Section 502(e)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(e)(1)(A)(i)) (the act) requires the label of a drug to bear the established name of the drug to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula). The established name of the drug is defined as

> * * *(A) the applicable official name designated pursuant to section 508 [of the act], or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient * * *.

(21 U.S.C. 352(e)(3))

Section 508 of the act (21 U.S.C. 358) authorizes FDA to designate an official name for any drug if FDA determines ''that such action is necessary or desirable in the interest of usefulness and simplicity'' (21 U.S.C. 358(a)). FDA does not, however, routinely designate official names for drug products under section 508 of the act (21 CFR 299.4(e)). In the absence of designation by FDA of an official name, interested persons may rely on the current compendial name as the established name (§ 299.4(e)). FDA has not designated an official name for water. The current compendial name for water is ''purified water,'' which should appear in product labeling.

III. The Technical Amendment

The agency is revising § 349.20 to state: ''The active ingredient of the product is purified water. The product also contains suitable tonicity agents to establish isotonicity with tears, suitable agents for establishing pH and buffering to achieve the same pH as tears, and a suitable preservative agent.'' The agency is also revising the statement of identity for eyewash drug products in § 349.78(a) to delete ''eye lotion'' and replace it with ''eye irrigation.'' The agency does not consider the term ''eye lotion'' fully informative to consumers in stating the purpose of the water in the eyewash drug product. Manufacturers should state the purpose of the water as either ''eyewash'' or ''eye irrigation.''

Section 201.66(c)(2) requires the labeling to state the quantity of each active ingredient. For products marketed without discrete dosage

directions, such as eyewashes, the labeling should state the proportion of each active ingredient. For eyewashes, the quantity of water should be stated as the percentage of the total product, which is likely to be 98 to 99 percent. It is not necessary to state ''in each bottle'' or an amount per dosage unit.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of agency procedure under 5 U.S.C. 553(b)(3)(A). Alternatively, the agency's implementation of this action without opportunity for public comment comes within the good cause exceptions in 5 U.S.C. 553(b)(3)(B) in that obtaining public comment is impracticable, unnecessary, and contrary to public interest. This labeling revision represents a minor clarifying change that does not change the substance of the labeling requirements contained in the final regulations. In accordance with 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on whether the regulation should be modified or revoked.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits 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 Executive Order 12866 and in these two statutes. The Unfunded Mandates Reform Act of 1995 does not require FDA to prepare a statement of costs and benefits for this final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation adjusted statutory threshold is about $110 million. No further analysis is required under the Regulatory Flexibility Act because the agency has determined that this final rule will not have a significant effect on a substantial number of small entities.

As discussed previously, FDA is implementing this action to clarify the final monograph for OTC ophthalmic drug products. This will facilitate compliance with the labeling provisions in § 201.66. OTC ophthalmic drug products were supposed to be in compliance with this section by May 16, 2002. The agency believes that while some products may have already incorporated the labeling format described in this technical amendment, other products have not.

The agency believes 25 manufacturers produce approximately 40 eyewash products, which are represented by up to 60 stock keeping units (SKUs). To minimize any impacts on any of these manufacturers not currently in compliance, the agency is providing them with up to 24 months (or the date of the first major labeling revision of the product after the effective date of this final rule, whichever occurs first) to relabel their products. The agency believes the cost of a label change to a particular SKU will not exceed $3,000. Based on this information, the total one-time costs of relabeling would be $180,000 ($3,000 per SKU x 60 SKUs). The average cost per manufacturer would be $7,200 ($180,000 / 25 manufacturers). These estimates likely overstate the true burden of this rule, as the agency believes some manufacturers may already be in compliance and would incur no additional costs. Also, some manufacturers might be able to make these changes during the implementation period as part of routinely scheduled label revisions.

The Regulatory Flexibility Act requires the agency to analyze whether a rule may have a significant impact on a substantial number of small entities. According to the Small Business Administration, manufacturers of OTC ophthalmic drug products, as part of the North American Industry Classification System (NAICS) code 325412 (pharmaceutical preparations), are small entities if they have fewer than 750 employees. The agency has reviewed information on the manufacturers of OTC eyewash drug products and believes 22 of the 25 manufacturers are small entities. These small entities have average annual revenues of $10.7 million. The cost of the rule per affected small entity would be 0.067 percent ($7,200 / $10.7 million) of average annual revenues.

The two smallest of these small entities have reported annual revenues of approximately $1 million. The agency believes one of these manufacturers to have three SKUs. The total cost of the final rule for this particular small entity would be 0.9 percent (3 SKUs x $3,000 per SKU / $1 million). Thus, the impact on any of the small entities would be less than 1 percent of annual revenues. The agency therefore certifies that this final rule will not have a significant impact on a substantial number of small entities.

V. Paperwork Reduction Act of 1995

The agency concludes that the labeling requirements 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 labeling 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)).

VI. 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.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Opportunity for Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or three hard copies

of any written comments, except that individuals may submit one hard 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 349

Labeling, Opthalmic 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 349.20 is revised to read as follows:

§ 349.20 Eyewashes.

The active ingredient of the product is purified water. The product also contains suitable tonicity agents to establish isotonicity with tears, suitable agents for establishing pH and buffering to achieve the same pH as tears, and a suitable preservative agent.

3. Section 349.78 is amended by revising paragraph (a) to read as follows:

§ 349.78 Labeling of eyewash drug products.

(a) *Statement of identity*. The labeling of the product identifies the product with one or more of the following terms: ''eyewash,'' ''eye irrigation,'' or ''eye irrigating solution.''

* * * * *

Dated: January 31, 2003.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 03–3926 Filed 2–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 636

[FHWA Docket No. FHWA–2000–7799]

RIN 2125–AE79

Design-Build Contracting

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Correction to final rule.

SUMMARY: This document corrects the final rule on design-build contracting published in the **Federal Register** on December 10, 2002 (67 FR 75902). The FHWA is correcting a typographical error concerning the relative weight of evaluation factors other than cost or price.

EFFECTIVE DATE: The final rule is effective January 9, 2003.

FOR FURTHER INFORMATION CONTACT: For technical information: Mr. Gerald Yakowenko, Office of Program Administration (HIPA), (202) 366–1562. For legal information: Mr. Harold Aikens, Office of the Chief Counsel (HCC–30), (202) 366–1373, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590–0001. Office hours are from 8 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

This document, the final rule, the NPRM, and all comments received by the U.S. Dockets Facility, Room PL–410, may be viewed through the Docket Management System (DMS) at *http://dms.dot.gov.* The DMS is available 24 hours each day, 365 days a year. Electronic submission and retrieval help and guidelines are available under the help section of this web site.

An electronic copy of this document may be downloaded by using a computer, modem and suitable communication software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661.

Internet users may reach the Office of the Federal Register's home page at: *http://www.archives.gov* and the Government Printing Office's Web site at: *http://www.access.gpo.gov/nara.*

Background

Section 1307 of the Transportation Equity Act for the 21st Century (TEA–21, Public Law 105–178, 112 Stat. 107 (1998)) amends 23 U.S.C. 112 to allow the design-build contracting method after the FHWA promulgates a regulation prescribing the Secretary's approval criteria and procedures on qualified projects. The TEA–21 defined qualified projects as projects that comply with the criteria in this regulation and whose total costs are estimated to exceed: (1) $5 million for intelligent transportation system projects, and (2) $50 million for any other project. It also provides certain key requirements that the FHWA must address in the development of these regulations.

On December 10, 2002, at 67 FR 75902, the FHWA published a final rule on Design-Build Contracting that implemented the regulations for design-build contracting as mandated by section 1307 of TEA–21. The regulations list the criteria and procedures that will be used by the FHWA in approving the use of design-build contracting by the State transportation departments. The regulation does not require the use of design-build contracting, but allows State transportation departments to use it as an optional technique in addition to traditional contracting methods.

After publication of the final rule, we realized that § 636.211(b)(2)(i) and (b)(2)(iii) read word for word identical to say, ''Significantly less important than cost or price.'' However, § 636.211(b)(2)(i) should read, ''Significantly more important than cost or price.'' This was stated clearly in the preamble to the final rule in the section-by-section analysis; however, when the rule language was typed in, both sections were identical, and the word ''less'' appeared in both sections. The FHWA is correcting § 636.211(b)(2)(i) to replace the word ''less'' with the word ''more.''

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action is not a significant regulatory action within the meaning of Executive Order 12866, or within the meaning of the U.S. Department of Transportation's regulatory policies and procedures because it is merely a correction of a minor mistake in the regulatory language. This correction will not adversely affect, in a material way, any section of the economy.

In addition, this correction to the rule will not interfere with any action taken or planned by another agency and will not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated the effects of this action on small entities and has determined that the final rule will not have a significant economic impact on a substantial number of small entities and hereby certifies that this correction to the final rule will not have a significant economic impact on a substantial number of small entities.