PART 73—SPECIAL USE AIRSPACE

1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.89 [Amended]

2. § 73.89 is amended as follows:

* * * * *

P–49 Crawford, TX [Amended]

By removing ''Boundaries. That airspace within a 3 NM radius of lat. 31°34′57″ N., long. 97°32′37″ W.,'' and substituting ''Boundaries. That airspace within a 3 NM radius of lat. 31°34′45″ N., long. 97°32′00″ W.,'' in its place.

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Issued in Washington, DC, on February 6, 2003.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 03–3964 Filed 2–18–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 30354; Amdt. No. 440]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration

ACTION: Final rule.

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

EFFECTIVE DATE: 0901 UTC, March 20, 2003.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards branch (AMCAFS–420), Flight technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd. Oklahoma City, OK. 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK. 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace Systems, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reason or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory change and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 95 Airspace, Navigation (Air).

Issued in Washington, DC, on February 10, 2003.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC.

1. The authority citation for part 95 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44719, 44721.

PART 95—[AMENDED]

2. Part 95 is amended to read as follows:

REVISIONS TO IFR ALTITUDES AND CHANGEOVER POINTS

[Amendment 440 Effective Date March/20/2003]

From	To	MEA
§ 95.6001 Victor Routes-U.S. § 95.6072 VOR Federal Airway 72 is Amended to Read in Part		
Dogwood, MO VORTAC	Gobey, MO Fix	3,400
Gobey, MO Fix	Maples, MO VORTAC	3.400
§ 95.6142 VOR Federal Airway 142 is Amended to Read in Part		
Malad City, ID VOR/DME	Fort Bridger, WY VOR/DME	12,000

REVISIONS TO IFR ALTITUDES AND CHANGEOVER POINTS—Continued

[Amendment 440 Effective Date March/20/2003]

From	To	MEA
§ 95.6289 VOR Federal Airway 289 is Amended to Read in Part		
Dogwood, MO VORTAC	GOBEY, MO FIX	3,400
GOBEY, MO FIX	Pekle, MO FIX	3,400
Pekle, MO FIX	Vichy, MO VOR/DME	3,000

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

BILLING CODE 4910–13–M

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