

## PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 USC 106(g), 40113, 44701.

### § 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Fokker: Docket 95–NM–170–AD.

*Applicability:* Model F28 series airplanes, excluding Model F28 Mark 0100 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

*Compliance:* Required as indicated, unless accomplished previously.

To prevent fatigue cracking of the elevator gust lock housing and the gust lock support structure, which could result in loss of the elevator and the support structure, and subsequent possible loss of primary pitch control, accomplish the following:

(a) Within 30 days after the effective date of this AD, perform a one-time detailed visual inspection to detect cracking of the elevator gust lock housing and the gust lock support structure, in accordance with Fokker Service Bulletin F28/55–30, Revision 1, dated January 4, 1993.

(b) If any cracking is found, prior to further flight, repair or replace the cracked elevator gust lock housing or gust lock support structure with a new or serviceable part in accordance with Fokker Service Bulletin F28/55–30, Revision 1, dated January 4, 1993. Use of the elevator gust lock system is prohibited until cracked parts are replaced with new or serviceable parts.

(c) 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, Standardization Branch, ANM–113, 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, Standardization Branch, ANM–113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(d) 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.

Issued in Renton, Washington, on March 26, 1996.

Darrell M. Pederson,

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 96–7853 Filed 3–29–96; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 886

[Docket No. 95N–0400]

RIN 0910–AA09

#### Medical Devices; Reclassification and Codification of Rigid Gas Permeable Contact Lens Solution; Soft (Hydrophilic) Contact Lens Solution; and Contact Lens Heat Disinfecting Unit

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to reclassify from class III (premarket approval) to class II (special controls) rigid gas permeable contact lens solution, soft (hydrophilic) contact lens solution, and the contact lens heat disinfection unit. Collectively, these devices are referred to as transitional contact lens care products, which include saline solutions, in-eye lubricating/rewetting drops, disinfecting and conditioning products, contact lens cleaners, and heat disinfecting units. This reclassification is in response to provisions in the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) and the Safe Medical Devices Act of 1990 (the SMDA). FDA is also amending the regulations for transitional contact lens care products to more accurately reflect the intent of the original regulation. Under the SMDA, FDA is implementing a special control that the agency has determined is necessary to provide reasonable assurance of the safety and effectiveness of the proposed reclassified contact lens care products. That special control is the availability of guidance for premarket notification submissions for these products. Elsewhere in this issue of the Federal Register, FDA is announcing the

availability of a draft guidance describing the evidence that demonstrates the substantial equivalence of new contact lens care products to contact lens care products already marketed.

**DATES:** Written comments by June 17, 1996. The agency proposes that any final rule that may issue based on this proposal become effective 30 days after date of publication of the final rule 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:** David M. Whipple, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2205.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The act (21 U.S.C. 321 *et seq.*), as amended by the 1976 amendments (Pub. L. 94–295) and the SMDA (Pub. L. 101–629), establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) establishes three classes of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: Class I, general controls; class II, special controls; and class III, premarket approval.

The 1976 amendments broadened the definition of “device” in section 201(h) of the act (21 U.S.C. 321(h)) to include certain articles that were once regulated as drugs. Under the 1976 amendments, Congress classified all transitional devices (i.e., those devices previously regulated as new drugs), including: Rigid gas permeable contact lens solutions; soft (hydrophilic) contact lens solutions; and contact lens heat disinfecting units, into class III (premarket approval). The legislative history of the SMDA reflects congressional concern that many transitional devices were being over regulated in class III. H. Rept. 808, 101st Cong., 2d sess. 26–27 (1990); S. Rept. 513, 101st Cong., 2d sess. 26–27 (1990). Congress amended section 520(l) of the act, (21 U.S.C. 360j(l)) to direct FDA to collect certain safety and effectiveness information from the manufacturers of transitional devices and review the classification of those still remaining in class III to determine if the device could be reclassified into class II (special controls) or class I (general controls).

Thus, in the Federal Register of November 14, 1991 (56 FR 57960), FDA, pursuant to section 520(l)(5)(A) of the act, issued an order requiring manufacturers of transitional devices, including rigid gas permeable contact lens solution (§ 886.5918 (21 CFR 886.5918)); soft (hydrophilic) contact lens solution (§ 886.5928 (21 CFR 886.5928)); and the contact lens heat disinfection unit (§ 886.5933 (21 CFR 886.5933)), to submit to FDA a summary of, and a citation to, any information known or otherwise available to them respecting the devices, including adverse safety or effectiveness information, which has not been submitted under section 519 of the act (21 U.S.C. 360i). Manufacturers were to submit the summaries and citations to FDA by January 13, 1992. However, because of misunderstandings and uncertainties regarding the information required by the order, and whether the order applied to certain manufacturers' devices, many transitional class III device manufacturers failed to comply with the reporting requirement by January 13, 1992. Thus, in the Federal Register of March 10, 1992 (57 FR 8462), FDA extended the reporting period to March 31, 1992.

Section 520(l)(5)(B) of the act (21 U.S.C. 360j(l)(5)(B)), stated that, after the issuance of an order requiring manufacturers to submit a summary of, and citation to, any information known or otherwise available respecting the devices, but before December 1, 1992, FDA was to publish regulations either leaving the transitional class III devices in class III or reclassifying them into class I or class II. Subsequently, as permitted by section 520(l)(5)(C) of the act (21 U.S.C. 360j(l)(5)(C)), in the Federal Register of November 30, 1992 (57 FR 56586), the agency published a notice extending the period for issuing such regulations until December 1, 1993. Due to limited resources, FDA was unable to publish regulations before the December 1, 1993, deadline. Nevertheless, in accordance with sections 520(l)(5)(B) and 513(a) of the act, FDA is now proposing to reclassify rigid gas permeable contact lens solution (§ 886.5918); soft (hydrophilic) contact lens solution (§ 886.5928); and the contact lens heat disinfection unit (§ 886.5933) from class III (premarket approval) to class II (special controls). FDA does not believe that these devices can be classified into class I because general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the devices. However, FDA does believe that these devices can be

classified into class II because sufficient information exists to establish special controls to provide reasonable assurance of their safety and effectiveness. The draft guidance entitled "Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products," the availability of which is being announced elsewhere in this issue of the Federal Register, is the special control that FDA believes is necessary to provide such assurance.

## II. Description of the Devices Proposed for Reclassification and Explanation of Proposed Modifications

The proposed reclassification and modifications are described below:

### A. Section 886.5918 Rigid Gas Permeable Contact Lens Care Products

FDA is proposing to change the classification title "Rigid gas permeable contact lens solution" to "Rigid gas permeable contact lens care products" to more accurately reflect the types of products classified under this regulation. Changing the word "solution" to "products" allows the agency to regulate other rigid gas permeable care products under this section.

FDA is also proposing to change the phrase "to clean, disinfect, wet, or store a rigid gas permeable contact lens" to "for use in the cleaning, conditioning, rinsing, lubricating/rewetting, or storing of a rigid gas permeable contact lens" to more accurately describe the intended use of contact lens care products rather than limit the description to solutions only. FDA does not consider this proposed modification a change in intended use for the following reasons:

1. Adding the word "rinsing" is proposed to accurately describe products (i.e., salines) approved under this classification for rinsing rigid gas permeable contact lenses;
2. Replacing the word "wet" with the phrase "lubricating/rewetting" is proposed to more accurately describe the intended use (i.e., in-eye) of lubricating and rewetting drops that have been approved for use with rigid gas permeable contact lenses; and
3. Replacing the word "disinfect" with the word "conditioning" is proposed because rigid gas permeable "disinfecting" solutions are more accurately called conditioning solutions. Not only are these solutions used to disinfect rigid gas permeable lenses, but they are also used to condition the surface of the lenses prior to insertion. The combination of these two intended uses, disinfecting and conditioning, is commonly referred to as

a conditioning solution when indicated for use with rigid gas permeable lenses.

Finally, FDA is proposing to add "This includes all solutions and tablets used together with rigid gas permeable contact lenses" to further clarify that tablets (i.e., enzyme tablets used for periodic cleaners) are also included in this proposed reclassification. Tablets were not included in the original regulation because, at the time of its issuance, these care products were not approved for use with rigid gas permeable lenses. However, this is no longer the case.

### B. Section 886.5928 Soft (Hydrophilic) Contact Lens Care Products

FDA is proposing to change the classification title "Soft (hydrophilic) contact lens solution" to "Soft (hydrophilic) contact lens care products" to more accurately reflect the intent of the original regulation. Changing the word "solution" to "products" allows the agency to regulate other soft (hydrophilic) contact lens care products (i.e., lens cases) under this section. It also allows FDA to include heat disinfecting units under this section.

FDA is also proposing to change the phrase "to clean, disinfect, wet, or store a soft (hydrophilic) contact lens" to "for use in the cleaning, disinfecting, rinsing, lubricating/rewetting, or storing of a soft (hydrophilic) contact lens" to more accurately describe the intended use of contact lens care products rather than limit the description to solutions only. FDA does not consider this modification a change in intended uses for the following reasons:

1. Adding the word "rinsing" is proposed because rinsing solutions have always been a part of the care regimen for soft (hydrophilic) contact lenses. FDA believes the word was inadvertently omitted from the original regulation; and
2. Replacing the word "wet" with the phrase "lubricating/rewetting" is proposed to more accurately describe the intended use (i.e., in-eye) of lubricating and rewetting drops that have been approved for use with soft (hydrophilic) contact lenses.

Finally, FDA is proposing to add "This includes all solutions and tablets used together with soft (hydrophilic) contact lenses and heat disinfecting units intended to disinfect a soft (hydrophilic) contact lens by means of heat" to further clarify that tablets (i.e., salt tablets used to make saline solutions, enzyme tablets used for periodic cleaners, and neutralizing tablets used to neutralize hydrogen peroxide disinfecting solution in soft

(hydrophilic) lenses) are also included in the proposed reclassification. This sentence also clarifies the fact that the heat disinfecting unit classification has been combined with the classification for soft (hydrophilic) contact lens care products.

*C. Section 886.5933 Contact Lens Heat Disinfecting Unit*

Finally, because FDA is proposing to classify contact lens heat disinfecting units in the same classification as other soft contact lens products, FDA is proposing to remove in its entirety the contact lens heat disinfecting unit classification (§ 886.5933), combine this classification with soft (hydrophilic) contact lens care products (§ 886.5928), and reclassify from class III (premarket approval) to class II (special controls) this proposed combined device.

**III. Summary of Reasons for the Proposed Reclassification**

The following are reasons in support of FDA's proposal to reclassify from class III to class II rigid gas permeable contact lens care products and soft (hydrophilic) contact lens care products, which include contact lens heat disinfecting units:

1. General controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the devices.

2. There is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the devices for their intended uses.

3. The special control, which is draft guidance entitled "Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products," describes the testing and information applicable to premarket notifications for the devices.

4. There is sufficient information to demonstrate that the devices are not potentially hazardous to the life, health, or well-being of the user. FDA has identified no new risks to health associated with the use of the devices, has determined that the identified potential risks to health can be addressed by using the special control (guidance), and that the probable benefits to health of the devices outweigh any probable risks to health.

FDA believes that current and future manufacturers of the devices can use the special controls draft guidance and that the safety and effectiveness of devices made by new manufacturers can be assured through the premarket notification procedures under section 510(k) of the act (21 U.S.C. 360(k)) as described in the special control draft

guidance. Consequently, FDA believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices.

**IV. Risks to Health**

The risks associated with the devices proposed for reclassification have been identified through over 25 years of FDA experience in the review and evaluation of the following publicly available information: (1) Preclinical and clinical data submitted in premarket approval applications (PMA's); (2) PMA annual reports and Mandatory Device Reporting (MDR) for contact lens devices; (3) scientific literature relating to contact lens devices; and (4) information submitted under section 520(l)(5)(A) of the act. A summary of the risks to health presented by each of the devices is described below:

1. Risks associated with use of rigid gas permeable and soft (hydrophilic) contact lens care products, other than contact lens heat disinfection units include:

Eye infection, irritation, burning and stinging, discomfort or pain, redness, excessive tearing, sensitivity to light, unusual secretions, dryness or vision changes; allergic, toxic or sensitivity reactions; damaged lenses which are caused by contaminated solutions; use of contact lens care products that fail to adequately perform their intended functions; sensitizing or toxic ingredients used in contact lens care product formulations; and inadequate labeling (e.g., warnings, precautions, and directions for use) for the safe and effective use of the device.

2. Risks associated with use of contact lens heat disinfection units include:

Fire, burns, or electrical shock; eye infections; damage to lenses caused by failure of the unit to adequately perform its intended function; and inadequate labeling (e.g., warnings, precautions, directions for use) for safe and effective use of the device.

Based upon FDA's experience in evaluating publicly available data and information contained in PMA's, PMA annual reports, MDR, and scientific literature, FDA has concluded that the risks to health associated with the use of the devices could be controlled by special controls. On the basis of its review, FDA now believes that use of the rigid gas permeable contact lens care products and soft (hydrophilic) contact lens care products, including contact lens heat disinfection units, do not present a potential unreasonable risk to the public health, and that special controls in the form of guidance to 510(k) submitters would provide

reasonable assurance of the safety and effectiveness of the device.

**V. Summary of Data Upon Which the Proposed Reclassification is Based (1)**

FDA based its proposed reclassification of contact lens care products on over 25 years of experience in the review and evaluation of publicly available preclinical and clinical data contained in: More than 100 PMA's; hundreds of PMA annual reports that included identification of adverse reactions reported for the device; the MDR data base within FDA; information submitted under section 520(l)(5)(A) of the act; and scientific literature for contact lens care products. From this experience in evaluating this information, FDA has identified the risks to health associated with these devices as listed in section IV. of this document and has developed product-specific "special controls" to address these risks for purposes of this reclassification proposal. On the basis of the review, FDA believes that use of the rigid gas permeable contact lens care products and soft (hydrophilic) contact lens care products, including heat disinfection units, does not present an unreasonable risk to the public health, and that the special controls will provide reasonable assurance of the safety and effectiveness of the devices.

The special control, the draft guidance entitled "Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products," sets forth the tests and information that FDA believes are needed to ensure the continued safety and effectiveness of contact lens care products. The guidance is organized into product specific sections that describe the information that addresses the risks associated with use of each device. In addition, the guidance will enable a manufacturer of a contact lens care product to conduct the necessary preclinical and clinical testing recommended in a 510(k) premarket notification to demonstrate substantial equivalence of the device to a legally marketed contact lens care product (predicate device).

The draft guidance outlines the types of manufacturing and chemistry, toxicology, and microbiology testing that should be completed for each device, and contains a summary of the basic requirements and suggested methods for meeting these preclinical requirements. If the results of preclinical testing demonstrate that the device will have new characteristics, clinical performance data may be needed to establish substantial equivalence. If clinical performance

data are needed, the draft guidance document provides suggested methodologies (e.g., size and scope of the study) to be included in the investigational protocol. This draft guidance document also provides general and product specific labeling guidance that identifies warnings, precautions, and directions for use that further address the risks associated with the use of these devices.

Other elements of the draft guidance include: (1) General information on the regulations and requirements for labeling contact lens care products; (2) information about 510(k) requirements relating to modifying a marketed contact lens care product; and (3) guidance for submitting a 510(k) for contact lens cases and contact lens accessories (i.e., mechanical cleaning aids and accessory cleaning pads).

The draft guidance explains that, in the event that clinical trials are necessary, manufacturers must conduct the trials in accordance with the investigational device exemption regulations in 21 CFR part 812. At this time, FDA considers clinical studies of most contact lens care products to be nonsignificant risk investigations. For nonsignificant risk investigations, approval of an institutional review board (IRB) is necessary before initiating a clinical study, and an investigational plan and informed consent document must be presented to an IRB for review and approval. Prior FDA approval is not required. However, FDA considers most clinical studies of solutions that contain new active ingredients for ophthalmic use and are intended for use directly in the eye to be significant risk investigations that would require both IRB and FDA review and approval.

#### VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a proposal on small entities. Because this proposal would reduce the regulatory burdens for all manufacturers of contact lens care products covered by this proposal, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Accordingly, FDA proposes to amend the regulations in §§ 886.5918, 886.5928, and 886.5933 as set forth below.

#### VIII. Effective Date

FDA is proposing that any final rule that may issue based on this proposed rule become effective 30 days after date of publication of the final rule in the Federal Register.

#### IX. Comments

Interested persons may, on or before June 17, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any 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. 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 886

Medical devices, Ophthalmic goods and services.

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 886 be amended as follows:

#### PART 886—OPHTHALMIC DEVICES

1. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 886.5918 is revised to read as follows:

#### § 886.5918 Rigid gas permeable contact lens care products.

(a) *Identification.* A rigid gas permeable contact lens care product is a device intended for use in the cleaning, conditioning, rinsing, lubricating/rewetting, or storing of a rigid gas permeable contact lens. This includes all solutions and tablets used together with rigid gas permeable contact lenses.

(b) *Classification.* Class II (Special Controls) Guidance Document: "Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products."

3. Section 886.5928 is revised to read as follows:

#### § 886.5928 Soft (hydrophilic) contact lens care products.

(a) *Identification.* A soft (hydrophilic) contact lens care product is a device intended for use in the cleaning, rinsing, disinfecting, lubricating/rewetting, or storing a soft (hydrophilic) contact lens. This includes all solutions and tablets used together with soft (hydrophilic) contact lenses and heat disinfecting units intended to disinfect a soft (hydrophilic) contact lens by means of heat.

(b) *Classification.* Class II (Special Controls) Guidance Document: "Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products."

#### § 886.5933 [Removed and Reserved]

4. Section 886.5933 *Contact lens heat disinfection unit* is removed and reserved.

Dated: March 18, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96-7784 Filed 3-29-96; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR PART 300

[FRL-5448-8]

#### National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of intent to delete the Washington County landfill from the National Priorities List; request for comments.

SUMMARY: The United States Environmental Protection Agency (U.S.