List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

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 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 721 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 379e).

2. Section § 172.841 is amended by revising paragraph (c) to read as follows:

§ 172.841 Polydextrose.

* * * * *

(c) Polydextrose is used in accordance with current good manufacturing practices as a bulking agent, formulation aid, humectant, and texturizer in the following foods when standards of identity established under section 401 of the act do not preclude such use: Baked goods and baking mixes (restricted to fruit, custard, and pudding-filled pies; cakes; cookies; and similar baked products); chewing gum; confections and frostings; dressings for salads; frozen dairy desserts and mixes; fruit spreads; gelatins, puddings and fillings; hard and soft candy; peanut spread; sweet sauces, toppings, and syrups; film coatings on single and multiple vitamin and mineral supplement tablets.

* * * * *

Dated: May 8, 1997.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–14752 Filed 6–5–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. 95N–0400]

Ophthalmic Devices: Reclassification 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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule reclassifying 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 accordance with 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). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance describing the evidence that may demonstrate the substantial equivalence of new contact lens care products to legally marketed predicate lens care products.

EFFECTIVE DATE: July 7, 1997.

FOR FURTHER INFORMATION CONTACT: James F. Saviola, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1744.

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), established 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 into class III all transitional devices (i.e., those devices previously regulated as new drugs). The legislative history of the SMDA reflects congressional concern that many transitional devices were being overregulated 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 still remaining in class III to determine whether the devices should be reclassified into class II (special controls) or class I (general controls). Accordingly, in the **Federal Register** of November 14, 1991 (56 FR 57960), FDA issued an order under section 520(l)(5)(A) of the act, 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 had 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. Consequently, 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, provides 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 transitional class III devices in class III or reclassifying them into class I or II. Subsequently, as permitted by section 520(l)(5)(C) of the act, 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 the regulations before the December 1, 1993, deadline.

In the **Federal Register** of April 1, 1996 (61 FR 14277), FDA published a proposed rule 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 disinfecting unit. The proposed rule contained reasons for the proposed reclassification, identified the risks to health presented by the device, and included a summary of the data upon which the proposed reclassification was based. Written comments were requested by June 17, 1996.

II. Summary and Analysis of Comments and FDA's Responses

Only one person from the public commented on the proposal. This comment stated that: (1) The proposed rule did not provide a rational basis for reclassification because it did not summarize, or provide a bibliography of, supporting safety and effectiveness information so that interested persons could challenge the proposal; (2) FDA was basing its reclassification on protected information in approved premarket approval applications (PMA's) and on information submitted in response to the order issued under section 520(l)(5)(A) of the act; and (3) the special control document only addresses safety issues and does not encompass device effectiveness.

FDA disagrees that the proposed rule did not provide a rational basis for reclassification of these devices. Section 520(l)(5)(B) states: ''In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 513(a).'' In accordance with those criteria, FDA has determined that special controls, in the form of the 510(k) guidance document would provide reasonable assurance of the safety and effectiveness of these devices. FDA made this determination based on its identification of the risks to health presented by these devices and on its review of preclinical and clinical data and adverse experience reports. FDA did not use information made available under section 520(h)(1) or (h)(2) of the act to ''establish the safety or effectiveness of another device'', as alleged by the comment.

The SMDA mandates that FDA review the classification of transitional devices and reclassify them into class I or class II unless FDA can justify requiring them to remain in class III. FDA has determined that premarket approval is not necessary for these devices because a special control entitled, ''Guidance for Industry; Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products,'' is sufficient to provide reasonable assurance of the safety and effectiveness of the devices. Consequently, FDA cannot justify requiring these devices to remain in class III.

FDA believes that it was Congress' intent that, whenever possible, FDA use the historical information and expertise it has obtained in reviewing scientific data to designate special controls that can be used as a basis for reclassifying devices. FDA has had over 25 years of experience in reviewing and evaluating preclinical and clinical data contained in more than 100 PMA's; hundreds of PMA annual reports that include identification of adverse reactions reported for the device; the medical device reporting (MDR) data base within FDA; information submitted under section 520(l)(5)(A) of the act; and volumes of scientific literature for contact lens care products. FDA did not publish a bibliography of literature articles supporting safety and effectiveness information because of the voluminous number of literature articles published for all of the devices included in this reclassification. FDA is not using data from PMA's to support reclassification of these devices and will not disclose protected information in approved PMA's.

FDA disagrees that the guidance document does not address effectiveness issues. Some examples of recommended testing to address effectiveness included in the document are cleaning effectiveness, compatibility testing, and clinical testing to confirm results of preclinical testing.

The same comment suggested that the agency clarify the classification status of contact lens cases.

At the January 26, 1995, meeting of the Ophthalmic Devices Panel, members unanimously recommended that contact lens cases be classified in class II. In the near future, FDA intends to publish a proposal in the **Federal Register** classifying contact lens cases in class II and including them under § 886.5928.

In accordance with sections 520(l)(5)(B) and 513(a) of the act, FDA is reclassifying 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 revised guidance document entitled, ''Guidance for Industry; 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.

III. Transitional Phase for Pending PMA's for Contact Lens Care Products

Below, FDA discusses how it will deal with the pending original and supplemental PMA's involving contact lens care products currently filed with the agency. As of today's date, all pending PMA applications will need to be examined to identify: (1) Those that are no longer subject to PMA review and can be converted to 510(k)'s or withdrawn and resubmitted to FDA by the sponsor to be evaluated through the 510(k) process; and (2) those that can be withdrawn by the sponsor and are not required to be resubmitted and evaluated as a 510(k) prior to implementing the request. FDA will make all final decisions on converted PMA's based on 510(k) regulatory requirements as elaborated in the document entitled, ''Guidance for Industry; Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.''

To ensure expeditious conversions, sponsors should review their pending PMA's and advise the agency as to what administrative action the sponsor believes needs to be taken regarding their pending applications affected by the reclassification. As of the effective date of this final rule, FDA will suspend the review of each pending original and supplemental PMA affected in whole or in part by this reclassification until the respective sponsor amends its application, setting forth the status of the device and the administrative action requested.

To convert a pending original or supplemental PMA to a 510(k), the sponsor should submit an amendment to the applicable PMA or supplemental PMA requesting that it be converted in total to a 510(k). The amendment should: (1) Request that the application be converted in total to a 510(k), (2) include a claim of substantial

equivalence to a previously approved contact lens care product (a product included in this reclassification), and (3) provide all 510(k) content requirements not submitted in the pending PMA or supplemental PMA, thus making the application as complete as possible when converted to a 510(k). Because preclinical and clinical data formerly required in a PMA may be necessary to support a substantial equivalence determination, a sponsor may provide references to applicable preclinical and clinical data contained in the sponsor's approved PMA('s) rather than duplicating the same data in a 510(k). When referencing data previously reviewed by the agency, the sponsor should clearly identify the relevant PMA number(s) and section(s) of the PMA or supplemental PMA. Pending original or supplemental PMA's converted to 510(k)'s will retain their position in the review queue (if they are complete), and the review process will continue without further delay.

To withdraw and resubmit a pending original or supplemental PMA, the sponsor should first submit an amendment to the applicable PMA requesting that it be withdrawn. The sponsor should then determine whether the request should be resubmitted and evaluated through the 510(k) process or be implemented without the need for submission of a 510(k). All original PMA's should be resubmitted as 510(k)'s. However, not all supplemental PMA requests require the submission of a 510(k). For example, unlike PMA's, under the 510(k) regulations, sponsors are not required to submit a 510(k) for an additional manufacturing site for a cleared device. To determine whether a 510(k) is required, the sponsor should consult the 510(k) procedures (21 CFR part 807) and the ''Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.'' Any required 510(k) submission should follow the content and format requirements for 510(k)'s. However, sponsors may provide references to preclinical and clinical data in the pending PMA or in approved PMA's rather than duplicating the data in a 510(k). When referencing data previously reviewed by the agency, the sponsor should clearly identify the relevant PMA number(s) and sections of the PMA or supplemental PMA. The sponsor should include in the 510(k) a claim of substantial equivalence to an applicable legally marketed contact lens care product (a product included in this reclassification) and a summary of safety and effectiveness information or a statement that the sponsor will make the safety and effectiveness information available to interested persons upon request.

To withdraw a pending supplemental PMA that contains a request that can be implemented without the need for submission of a 510(k), the sponsor should submit an amendment to the applicable supplemental PMA requesting that it be withdrawn.

In addition, sponsors should determine if there is information in the pending PMA that would not be needed when resubmitted as a 510(k) application. In making this determination, FDA cautions sponsors to review the regulations pertaining to releasability of information in PMA's and 510(k) submissions since different disclosure rules apply to PMA's and 510(k) submissions. For this reason, a manufacturer may choose not to have a pending PMA converted to a 510(k) submission, but instead choose to withdraw the pending application, purge it of unnecessary information that the sponsor might not want released, and resubmit the relevant data in a new 510(k) submission.

If a sponsor fails to submit an amendment as outlined above within 180 days of the effective date of reclassification, FDA will consider the pending PMA or PMA supplement to be voluntarily withdrawn. In such cases, the agency will notify the sponsor by letter of the withdrawal. All amendments to pending PMA's shall include the PMA or PMA supplement number and shall be addressed to the PMA Document Mail Center (HFZ–401), Center for Devices and Radiological Health, Office of Device Evaluation, 9200 Corporate Blvd., Rockville, MD 20850. Additional questions regarding administrative procedures resulting from this reclassification should be directed to the PMA Staff (Kathy Poneleit, 301–594–2186), or to the Division of Ophthalmic Devices, Vitreoretinal and Extraocular Devices Branch (James F. Saviola, or Muriel Gelles, 301–594–1744.)

IV. 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.

V. Analysis of Impacts

FDA has examined the impacts of the final 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). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, 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.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule would reduce the regulatory burdens for all manufacturers of contact lens care products covered by this rule, the Commissioner of Food and Drugs certifies that the final 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 is amending the regulations in §§ 886.5918, 886.5928, and 886.5933 as set forth below.

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, 21 CFR part 886 is 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:

''Guidance for Industry 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 of 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: ''Guidance for Industry 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: May 28, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–14751 Filed 6–5–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD01–97–009]

RIN 2115–AE46

Special Local Regulation: Fireworks Displays Within the First Coast Guard District

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is revising the special local regulation for annual fireworks displays in the First Coast Guard District. The final rule includes additional fireworks displays and arranges the events listed in Table 1 by event date. This regulation is necessary to control vessel traffic within the immediate vicinity of the fireworks launch sites and to ensure the safety of life and property during each event.

DATE: Effective June 23, 1997.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander James B. Donovan, Office of Search and Rescue, First Coast Guard District, (617) 223–8268.

SUPPLEMENTARY INFORMATION:

Regulatory History

A notice of proposed rulemaking (NPRM) was published on April 21, 1997, (62 FR 19240) in the **Federal Register** proposing to update the permanent special local regulation for the annually recurring fireworks displays in the First Coast Guard District. The Coast Guard received no comments on the proposed rulemaking. A public hearing was not requested and one was not held.

Background and Purpose

Each year, organizations in the First District sponsor fireworks displays in the same general location during the same general time period. The Coast Guard is updating the special local regulation at 33 CFR 100.114 which provides a regulated area surrounding the launch platform used during each fireworks display. Table 1 of the regulation provides dates and locations for the annual fireworks events. This final rule updates Table 1 by adding and deleting several events. Table 1 has also been revised to list the events in chronological order to ease administration by the Coast Guard and provide better notice to the public.

Each event listed in Table 1 will use a barge or on-shore site as the fireworks launch platform. The special local regulation controls vessel movement within a 500 yard radius around the launch platform to ensure the safety of persons and property at these events. In the event the fireworks are launched from shore, the regulated area only includes navigable waters that fall within a 500 yard radius of the launch site. Coast Guard personnel on-scene may allow persons within the 500 yard radius should conditions permit. The Coast Guard publishes notices in the **Federal Register** each year which provide the exact dates and times for these events.

Good cause exists for this rule to become effective in less than 30 days. Due to the need to publish notice in the **Federal Register** of the exact dates and times of each event and the necessity to have the regulation in effect for events celebrating the Fourth of July, this final rule is being made effective in less than 30 days after publication. Any delay encountered in making this rule effective would be contrary to the public interest as the rule is needed to ensure the safety of the boating public during these events.

Discussion of Changes

No comments were received. The Coast Guard has deleted the Museum of Science Memorial Day Fireworks and the Yampol Family Fireworks from Table 1. Both events are no longer held. Also, the Macys' July 4th Fireworks Display has been deleted from Table 1 since it is not an appropriate event for inclusion in section 100.114.

Regulatory Evaluation

This proposal is not a significant regulatory action under Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been reviewed by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). Due to the short duration of each fireworks display, the advance notice provided to the marine community, and the small size of each regulated area, the Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation, under paragraph 10e of the regulatory policies and procedures of DOT, is unnecessary.

Small Entities

The Coast Guard has considered the economic impact of this rule on small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) For the reasons discussed in the Regulatory Evaluation, the Coast Guard has determined that this rule will have no significant economic impact on small entities. If, however, you think that your business or organization qualifies as a small entity and that this rule will have a significant economic impact on your business or organization, please submit a comment explaining why you think it qualifies and in what way and to what degree this rule will economically affect it.

Collection of Information

This proposal contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this proposal under the principles and criteria contained in Executive Order 12612 and has determined that this proposal does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.