and there was only one other competitor in the market for general acute care hospital services in Berks County, Pennsylvania, according to the complaint. The consolidation allegedly made the market highly concentrated, raising BHS' market share to over 75%. The market also is difficult for new competitors to enter, according to the complaint. The complaint charges that until the consolidation was rescinded (as described below), its effect may have been to substantially lessen competition in the Berks County hospital market, in violation of section 7 of the Clayton Act.

According to the complaint, on January 18, 1989 Reading Hospital and Community General agreed to rescind their consolidation. BHS relinquished its control of Community General in late March 1989. Soon thereafter, Community General's representation on the BHS board of directors was terminated. BHS was subsequently dissolved in December 1989. As a result, Reading Hospital and Community General are once more independent competitors in the Berks County hospital market.

The Proposed Consent Order

The first paragraph of the proposed order defines the respondents subject to the order, and certain other terms used in the order. Paragraph II would prohibit respondents from acquiring, directly or indirectly, without the prior approval of the Federal Trade Commission, all or part of any hospital in Berks County, Pennsylvania. it would also prohibit respondents from transferring any hospital they operate in Berks County to a person that operates or is acquiring a hospital in Berks County. The coverage of paragraph II would be limited to acquisitions of hospitals or their assets where the purchase price, or fair market value in the case of non-purchase acquisitions (such as leases or management contracts), is more than $1,000,000. Paragraph II would expire ten years after the order becomes final.

Paragraph III of the proposed order would prohibit, for ten years, respondents from transferring any of their hospitals in Berks County to a non-respondent without first filing with the Commission an agreement by the transferee to be bound by the order (including the requirements of Paragraph III), or obtaining prior approval from the Federal Trade Commission for not requiring such an agreement. Paragraphs II and III, in combination, would give the Commission authority to prohibit transactions combining the general acute care hospital operations of Reading Hospital and Community General, or of one of those firms and any other general acute care hospital in Berks County, unless the parties convinced the Commission that a particular transaction would not endanger competition in the Berks County hospital market.

Paragraph IV of the proposed order requires respondents to make certain documents and personnel available to the Federal Trade Commission upon written request for the purpose of verifying compliance with the order. Paragraph V of the proposed order requires respondents to notify the Commission at least thirty days before any proposed change in corporate structure that may affect compliance with the order.

The proposed order does not require divestiture. According to the complaint, the affiliation of Community General with BHS and Reading Hospital has ended, and Community General is once again an independent competitor. Community General has settled all outstanding financial obligations resulting from its affiliation with BHS and Reading Hospital. Community General has arranged participation in its own right in a group supply purchasing agreement to which it had access as a BHS affiliate. It has also elected to continue purchasing biomedical equipment maintenance, laboratory and laundry services from Reading Hospital (but is transferring its data processing work from Reading Hospital to a non-hospital vendor), and both Community General and Reading Hospital continue as member hospitals of Berkshire Health Plan, a hospital-sponsored preferred provider organization. Otherwise, the two hospitals now operate independently of each other. The Commission has concluded that Community General is a viable, independent competitor, and that no relief beyond that contained in the proposed order is needed to restore Community General and the Berks County hospital market to their approximate pre-affiliation competitive positions.

The purpose of this analysis is to invite public comment concerning the proposed order, to assist the Commission in its determination whether to make the order final. This analysis is not intended to constitute an official interpretation of the agreements and the proposed order or to modify their terms in any way.

The agreements are for settlement purposes only and do not constitute admissions by Reading Hospital or Community General that the law has been violated as alleged in the proposed complaint.

Donald S. Clark,

Secretary.

[FR Doc. 90-2147 Filed 1-30-90; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 80N-0140]

RIN 0905-AC48

Juice and Diluted Juice Beverages; Common or Usual Name for Nonstandardized Foods

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has received a petition from the National Food Processors Association (NFPA) requesting that the agency initiate rulemaking to replace the common or usual name regulation for diluted fruit or vegetable juice beverages other than diluted orange juice beverages (21 CFR 102.33) with a new regulation. The new regulation that NFPA has suggested would require, among other things, that the percentage of juice contained in a juice or diluted juice beverage be declared on the information panel, if one is present, rather than on the principal display panel. FDA is requesting that interested persons comment on this petition. FDA is also requesting comments on how to accurately represent the contents of juice blend products and diluted juice blend products containing one or more characterizing flavors, and comments on the general issue of the common or usual name regulation for diluted juice beverages (§ 102.33), including naming diluted juice beverages containing modified juices. FDA will consider all of the comments that it receives, as well as previously submitted comments and the NFPA petition, in devising its next action regarding the diluted juice beverage regulation (§ 102.33).

DATES: Written comments by April 2, 1990.

ADDRESSES: Written comments on this citizens petition or any other related matter are to be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-62, Fishers Lane, Rockville, Md 20857.

FOR FURTHER INFORMATION CONTACT: Terry C. Troxell, Center for Food Safety

and Applied Nutrition (HFF–312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–485–0229.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 10, 1980 (45 FR 39247), FDA published a final rule establishing the common or usual name for diluted fruit of vegetable juice beverages other than diluted orange juice beverages (21 CFR 102.33), to be effective July 1, 1981. The regulation would have required that all diluted juice beverages other than diluted orange juice beverages be labeled with a descriptive name identifying the beverage and with a percentage declaration of the amount of juice contained in the beverage.

FDA extended the effective date of the regulation on three occasions, the most recent being June 27, 1984 (49 FR 26541), when the agency extended the effective date indefinitely. Just before the indefinite extension, in the **Federal Register** of June 1, 1984 (49 FR 22831), FDA proposed to amend 21 CFR 102.33 to: (1) Exempt cranberry juice products from the requirement that the percentage of juice in diluted juice beverages be declared on the label; (2) allow the manufacturers of other diluted high-acid juice beverages to petition for a similar exemption; (3) eliminate the requirement that the percentage of individual juices in diluted multiple-juice beverages be declared on the label; and (4) permit declaration of the percentage of juice in a product as a whole number not greater than the actual percentage contained in the beverage rather than in 5 percent increments. In the **Federal Register** of July 16, 1987 (52 FR 26690), FDA withdrew the June 1, 1984, proposal and proposed to revoke this common or usual name regulation (21 CFR 102.33).

II. NFPA Petition

FDA has now received a citizen petition from NFPA dated January 19, 1989 (Docket No. 80N–0140, initially assigned Docket No. 89P–0025/CP), requesting that the agency revoke the current common or usual name regulation for diluted fruit or vegetable juice beverages other than diluted orange juice beverages (21 CFR 102.33) and initiate the appropriate action to provide for a new § 102.33.

The replacement regulation that NFPA is proposing is entitled, "Common or Usual Name Regulation for Juices and Diluted Fruit or Vegetable Juice Beverages other than those that conform to a standard of identity or a separate common or usual name regulation." It states:

(a) *§ 102.33(a).* The common or usual name of a noncarbonated beverage containing more than zero percent fruit or vegetable juice(s) (other than a juice or beverage that conforms to a definition and standard of identity or to a separate common or usual name regulation) shall be a descriptive name meeting the requirements of § 102.5(a) (e.g., "apple juice", "diluted grape juice beverage", "grape juice drink", or another descriptive phrase).

(b) The percentage of total juice contained in the product shall be declared by the words "containing (or contains) _____ percent (or percent) _____ juice" or "_____ percent (or percent) _____ juice", with the first blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the juice and the second blank filled in with "fruit" or "vegetable" or with the name of the particular fruit or vegetable if the product contains only one juice. Such statement shall be in easily legible boldface print or type in distinct contrast to other printed or graphic matter, in a height not less than the height of the required declaration of net quantity of contents on the label, and in lines generally parallel to the base on which the package rests.

(1) If the package has an information panel as defined in § 101.2, the statement of the percent of total juice content shall appear near the top of the information panel, with no other printed label information appearing above the statement.

(2) If the package has only a principal display panel and does not have an information panel, the statement of percent of total juice content shall appear prominently and conspicuously on the principal display panel.

(c) The percent of fruit or vegetable juice(s) in a diluted juice beverage shall be calculated on the basis of the soluble solids content of the single-strength (undiluted) juice(s) used to prepare the diluted beverage and shall be declared on a volume/volume basis. If the finished beverage is prepared from concentrated juice(s), the percent of fruit or vegetable juice(s) shall be calculated on the basis of soluble solids content of the single-strength (unconcentrated) juice(s) used to produce such concentrated juice(s). The soluble solids content of single-strength high-acid juice (lemon, lime, or cranberry juice) shall be the weight of soluble solids obtained from refractometer readings corrected for acidity as set forth in § 22.025, Official Methods of Analysis of the Association of Official Analytical Chemists, 14th Ed. (1984), which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists (new address: Suite 400–BW, 2200 Wilson Boulevard, Arlington, VA 22201–3301) or available for inspection at the office of the Federal Register, 1100 L Street NW., Washington, DC 20408.

NFPA also requested that FDA withdraw the proposal that was published in the **Federal Register** of June 1, 1984 (49 FR 22831). The agency points out that, as discussed above, it did so in the **Federal Register** of July 16, 1987 (52 FR 26690).

The NFPA proposal differs from the current 21 CFR 102.33 in several respects. First, NFPA would require that the declaration of the percentage of juice contained in a produce be placed prominently on the information panel (or, in the absence of an information panel, prominently on the principal display panel) rather than as part of the statement of identity on the principal display panel (21 CFR 102.33(a)). NFPA would require that this declaration be made on the label of juices as well as on the label of diluted juice beverages. Secondly, NFPA would only require the declaration of the total percentage of juice in a multiple juice beverage. It would not require, as current § 102.33(a)(2)(ii) (21 CFR 102.33(a)(2)(ii)) does, a declaration of the percentage of individual juices in beverages that contain multiple juices but that have a label or labeling that makes representations, either directly or indirectly, about the characterizing juice. Finally, NFPA would require that the percentage of juice contained in a product be expressed as a whole number that is not greater than the actual percentage rather than in 5 percent increments, as is required in the current regulation (21 CFR 102.33(a)(2)). NFPA did not suggest changing the method of determining the percentage of juice in diluted juice beverages.

NFPA stated that its petition was the work of a special NFPA task force that NFPA convened to develop a consensus that would both receive general support from the various segments of the juice industry and provide useful, nonconfusing information in the labeling of these products to the consuming public.

In conjunction with this petition, the NFPA task force concluded that the products described in the petition should bear nutrition labeling that would allow consumers to "evaluate all products not only on the basis of taste, refreshment and juice content, but also on the basis of the contribution they make to nutrition." Consequently, the task force concluded that NFPA should initiate proposals in Congress for an amendment to the Federal Food, Drug, and Cosmetic Act (the act) that would authorize FDA to require nutrition labeling for this category of food products. The two prongs of this approach are being pursued independently of each other by NFPA.

FDA has received two substantive comments on the NFPA petition. The Coalition of Responsible Juice Companies (CRJC) requests that FDA set an effective date as soon as possible for 21 CFR 102.33, and that diluted juice

beverages bear a principal display panel disclosure of the percentage of total juice, with no exemptions for any juice. CRJC points out that FDA could alter the regulation later, if warranted, in response to public comment on the NFPA petition.

The Center for Science in the Public Interest (CSPI) states that FDA should require percentage declaration on diluted juices as soon as possible and believes that the percentage declaration should be on the principal display panel. However, the comment states, if FDA chooses to require such disclosure on the information panel, FDA should insure that the disclosure is highly visible. In addition, CSPI believes that if the information panel is designated, manufacturers should be given the option to make the percentage disclosure on the principal display panel.

These comments will be considered as part of FDA's rulemaking. They are available for review in the Dockets Management Branch (address above) under Docket No. 80N-0140.

III. Characterizing Flavor of Blended Juice Products

FDA is also concerned about accurately representing the contents of multiple juice products and diluted multiple juice products that contain minor amounts of the characterizing juice (that is, the juice that imparts a dominant or distinguishing flavor to the product), whether or not the characterizing juice has been enhanced with added flavoring. This issue is especially important if the declaration of the percentage of the juice in a product is moved from the principal display panel to the information panel and only the total percentage of juice is declared. The primary concern is to accurately represent the contents of the product while not providing misleading information to the consumer. For example, a label would be misleading if it implied that the characterizing juice is either the only juice or the major juice present in the product when it is not.

Different approaches have been suggested by NFPA, FDA, and others as to how to accurately name diluted multiple juice products that contain minor amounts of the characterizing juice. One option includes the following elements: (1) Naming the product with the name of the characterizing juice or flavor regardless of whether that juice is present in the greatest amount; (2) using the word "blended" or "blend" of juices; and (3) not using the word "flavored," even though the product may be enhanced with natural flavor derived from the characterizing juice, unless the declared juice alone would not be the characterizing juice. Based on this option, a firm might consider it appropriate, for example, to label a grape/pear/raspberry juice blend that contains a minor amount of raspberry juice, but enough to impart a raspberry flavor to the juice, as "raspberry—a blend of three juices" or "raspberry juice blend." A similar product to which a natural raspberry flavor is added could be labeled the same way. Other labeling options include adding the word "flavored" to the name of such a product, e.g., "raspberry-flavored juice blend;" requiring as a product name "(name of characterizing juice) juice in a (blend, mixture, or base) of (number) other fruit juices," e.g., "Raspberry juice in a blend of two other fruit juices;" or requiring that all juices in the mixture be listed, either in an order of predominance (most present) or prominence (most apparent by taste).

The question also arises as to how to properly use vignettes that depict, usually in pictures, the fruits in a diluted multiple juice product with a characterizing juice. At issue here is whether to depict the fruits in such products by showing more of the fruit that is most apparent in taste (prominence) or that is present in the greatest quantity (predominance).

FDA is seeking comments on how to accurately represent, through identity statements and vignettes, diluted juice blend products with one or more characterizing juices (with or without noncharacterizing juices). The comments should address the consistency of the suggested labeling approaches with: (1) The labeling provisions of the act; (2) the regulations governing the common or usual name for nonstandardized foods (21 CFR 102.5); (3) the flavor labeling regulations found in 21 CFR 101.22(i); (4) the common or usual name for diluted fruit or vegetable juices found in 21 CFR 102.33 (effective date extended indefinitely); and (5) any other pertinent regulations.

IV. Modified Juices

Because diluted fruit and vegetable juices are sometimes made with modified juices, FDA believes that modified juices should be included among the matters considered in this proceeding. FDA has been concerned for the last several years about modified juices, including decharacterized or stripped juices. The modifications in these juices range from relatively minor changes, such as altering the acidity to improve the taste, to major modifications that remove virtually all flavors and colors, and resulting essentially in sugar water. At issue is how a juice that has been altered by a treatment (e.g., ion exchange) that removes or replaces the constituents (such as flavors, colors, and acids) by which consumers recognize the original juice should be identified on the label.

If a modified juice is represented as the unmodified juice or is used as a component in a juice product as though it were the unmodified juice, it may result in economic deception of the consumer. For example, consumers would be economically deceived if deflavored, decolored, acid-reduced grape juice was used in a product, such as raspberry-flavored juice beverage, that was labeled with respect to the percentage of juice and to ingredient content as though the decharacterized grape juice was an unaltered juice.

FDA also is concerned that in modifying these juices, important components of the juice, such as potassium, are stripped from the juice, and other, undesirable, substances, like sodium, are added. As a result, an individual who has been advised by his physician to drink a particular juice because of its high potassium content, or who has been advised to avoid sodium, may receive something other than what he or she expects when consuming modified juices represented as ordinary juices.

The use of modified juices thus raises at least two issues. First, to be informative to consumers, to comply with the labeling provisions of section 403 of the act (21 U.S.C. 343), and to not violate the economic adulteration provisions of section 402(b) of the act (21 U.S.C. 342(b)), a modified juice product, whether sold as a single component beverage or as an ingredient in a multicomponent beverage, must be properly named. In the past, FDA has considered names such as "Acid-Reduced Apple Juice" or "Decolored, Deflavored, Acid-Reduced Grape Juice" to be appropriately descriptive names. However, names that end with the word "juice" may be misleading to consumers, who have come to associate the term "juice" with the unmodified expressed juice of a fruit or vegetable and to associate names such as "juice beverage" and "juice drink" with a product that is something less than the unmodified expressed juice of a fruit or vegetable. FDA is asking for comments on how modified juice products should be labeled so as not to deceive consumers.

Secondly, the agency has in the past expressed the opinion that these modified juice products should not be included as juices in determining the total percentage of juice in a diluted

juice beverage because they are no longer the unaltered liquid of the source fruit or vegetable. FDA is asking for comments on this view. Comments should consider whether any modification of a juice would be so minor that the modified juice may be considered a juice for calculating the juice percentage in a diluted juice beverage. Comments should address methods for FDA enforcement of any approach suggested that permits juice with minor modifications to be included when calculating the percentage of juice in a diluted juice beverage.

V. Agency Options

Because of the unresolved issues regarding naming diluted juice beverages, including the proposed revocation of 21 CFR 102.33, the agency has concluded that it would be in the best interest of all concerned to request comments on the entire issue of the common or usual name regulation for diluted juice beverages (§ 102.33) before FDA begins its review of the NFPA petition or takes any other action on this common or usual name regulation. Therefore, in accordance with 21 CFR 10.30(h)(3), FDA is requesting that all interested persons comment on any aspect of the common or usual name regulation for diluted juice beverages (§ 102.33), including the final rule of June 10, 1980 (45 FR 39247), establishing § 102.33; the proposal of July 16, 1987 (52 FR 26690), to revoke § 102.33; the NFPA petition; juice blend products and diluted juice blend products containing one or more characterizing juices; modified juices; the other considerations discussed in this notice; and any economic impact on affected parties. FDA requests that all comments submitted reference Docket No. 80N–0140.

In determining its next action on the common or usual name regulation for diluted juice beverages other than diluted orange juice beverages, the agency will consider the comments received on this notice and on relevant previous notices. Based on its evaluation of these comments, the agency may: (1) Propose a new effective date for § 102.33; (2) propose a new effective date for parts of § 102.33 and propose revisions for the other parts of that regulation; (3) propose to replace § 102.33 with NFPA's suggested regulation or a modification thereof; (4) propose to replace § 102.33 with a labeling regulation that is substantially different from both the existing § 102.33 and NFPA's suggested regulation; or (5) revoke § 102.33.

The agency encourages interested persons to obtain copies of the NFPA petition to facilitate review and comment. Any request for a copy of the petition should be submitted in writing to the Freedom of Information Staff (HFR–35), Food and Drug Administration, RM. 12A–16, 5600 Fishers Lane, Rockville, MD 20857. Requests should reference Docket No. 80N–0140.

Interested persons may, on or before April 2, 1990, submit to the Dockets Management Branch (address above) written comments regarding this petition or any other matter relating to the common or usual name of diluted juice products. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with Docket No. 80N–0140. The citizen petition and the received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 19, 1990.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 90–2097 Filed 1–30–90; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 90F–0017]

National Starch and Chemical Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that National Starch and Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of *beta*-amylase to treat modified food starch.

FOR FURTHER INFORMATION CONTACT: Eric L. Flamm, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–8950.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that National Starch and Chemical Corp., Finderne Ave., P.O. Box 6500, Bridgewater, NJ 08807, has filed a petition (FAP 9A4136), proposing that the food additive regulations be amended to provide for the safe use of *beta*-amylase to treat modified food starch.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: January 24, 1990.

Douglas L. Archer,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 90–2170 Filed 1–30–90; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 90M–0006]

CIBA Vision Corp.; Premarket Approval of CIBA 2000™ Spherical (Atlafilcon A) Soft (Hydrophilic) Contact Lenses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by CIBA Vision Corp., Atlanta, GA, for premarket approval, under the Medical Device Amendments of 1976, of the spherical CIBA 2000™ Spherical (atlafilcon A) Soft (Hydrophilic) Contact Lenses for daily wear. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 28, 1989, of the approval of the application.

DATES: Petitions for administrative review by March 2, 1990.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David M. Whipple, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301–427–1080.

SUPPLEMENTARY INFORMATION: On May 3, 1989, CIBA Vision Corp., Atlanta, GA 30360, submitted to CDRH an application for premarket approval of the CIBA 2000™ Spherical (atlafilcon A) Soft (Hydrophilic) Contact Lenses. The spherical lenses are indicated for daily wear for the correction of visual acuity in not-aphakic persons with nondiseased eyes that are myopic or hyperopic. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters (D) or less that does not

interfere with visual acuity. The spherical lenses range in powers from −20.00 D to +12.00 D and are to be disinfected using a heat, chemical, or hydrogen peroxide lens care system.

On October 20, 1989, the Ophthalmic Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On December 28, 1989, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact David M. Whipple (HFZ–460), address above. The labeling of the CIBA 2000™ Spherical (atlafilcon A) Soft (Hydrophilic) Contact Lenses states that the lens is to be used only with certain solutions for disinfection and other purposes. The restrictive labeling informs new users that they must avoid using certain products, such as solutions intended for use with hard contact lenses only.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be used in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before March 2, 1990, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commission of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: January 23, 1990.

John C. Villforth,

Director, Center for Devices and Radiological Health.

[FR Doc. 90–2168 Filed 1–30–90; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 90M–0005]

Storz Ophthalmics, Inc.; Premarket Approval of Models 120UV, S120UV, 120JUV, S120JUV, 120MUV, S120MUV, 120WUV, S120WUV, 120YUV, and S120YUV Ultraviolet-Absorbing Anterior Chamber Intraocular Lenses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Storz Ophthalmics, Inc., Clearwater, FL, for premarket approval under the Medical Device Amendments of 1976 (the amendments) of the Models 120UV, S120UV, 120JUV, S120JUV, 120MUV, S120MUV, 120WUV, S120WUV, 120YUV, and S120YUV Ultraviolet-Absorbing Anterior Chamber Intraocular Lenses. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 28, 1989, of the approval of the application.

DATES: Petitions for administrative review by March 2, 1990.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy C. Brogdon, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301–427–1212.

SUPPLEMENTARY INFORMATION: On November 14, 1988, Storz Ophthalmics, Inc., Clearwater, FL 34616, submitted to CDRH an application for premarket approval of the Models 120UV, S120UV, 120JUV, S120JUV, 120MUV, S120MUV, 120WUV, S120WUV, 120YUV, and S120YUV Ultraviolet-Absorbing Anterior Chamber Intraocular Lenses (IOL's). These devices are indicated in patients 60 years of age and older: (1) where a cataractous lens has been removed following primary intracapsular cataract extraction (ICCE), (2) after a primary extracapsular cataract extraction (ECCE) where there is a structural reason that the anterior chamber lens is preferred to a posterior one, or (3) in a secondary implant procedure. Implantation after primary ECCE should be performed only after the physician has compared the published results of the anterior chamber lens with posterior chamber lenses. The devices are available in a range of powers from 4 diopters (D) through 34 D in 0.5–D increments.

On October 19, 1989, the Ophthalmic Devices Panel, and FDA advisory committee, reviewed and recommended approval of the application. On December 28, 1989, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

Under the amendments, IOL's are regulated as class III devices (premarket approval).

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact Nancy C. Brogdon (HFZ–460), address above.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request