Supplement No. 1 to Part 786

FOREIGN TRADE STATISTICS REGULATIONS OF THE BUREAU OF THE CENSUS; SUBPART D—EXEMPTIONS FROM THE REQUIREMENTS FOR THE FILING OF SHIPPER'S EXPORT DECLARATION (15 CFR 30.50–30.58)

* * * * *

Dated: January 4, 1993.

James M. LeMunyon,

Acting Assistant Secretary for Export Administration.

[FR Doc. 93–303 Filed 1–7–93; 8:45 am]

BILLING CODE 3510–DT–M

FEDERAL TRADE COMMISSION

16 CFR Part 305

RIN 3084–AA26

Rules for Using Energy Cost and Consumption Information Used in Labeling and Advertising of Consumer Appliances Under the Energy Policy and Conservation Act; Ranges of Comparability for Refrigerators, Refrigerator-freezers, and Freezers

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission amends its Appliance Labeling Rule by revising the ranges of comparability used on required labels for refrigerators, refrigerator-freezers, and freezers.

Under the rule, each required label on a covered appliance must show a range, or scale, indicating the range of energy costs or efficiencies for all models of a size or capacity comparable to the labeled model. This notice publishes the new range figures, which, under §§ 305.10, 305.11 and 305.14 of the rule, must be used on labels on refrigerators, refrigerator-freezers, and freezers manufactured on and after April 8, 1993 and in advertising of refrigerators, refrigerator-freezers, and freezers in catalogs printed after April 8, 1993. Properly labeled refrigerators, refrigerator-freezers, and freezers manufactured prior to the effective date need not be relabeled. Catalogs printed prior to the effective date in accordance with 16 CFR 305.14 need not be revised.

EFFECTIVE DATE: April 8, 1993.

FOR FURTHER INFORMATION CONTACT: James Mills, Attorney, 202–326–3035, Division of Enforcement, Federal Trade Commission, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: On November 19, 1979, the Commission issued a final rule,[1] pursuant to section 324 of the Energy Policy and Conservation Act of 1975,[2] covering certain appliance categories, including refrigerators, refrigerator-freezers, and freezers. The rule requires that energy costs and related information be disclosed on labels and in retail sales catalogs for all refrigerators, refrigerator-freezers, and freezers presently manufactured. Certain point-of-sale promotional materials must disclose the availability of energy usage information. If a refrigerator, refrigerator-freezer or freezer is advertised in a catalog from which it may be purchased by cash, charge account or credit terms, then the range of estimated annual energy costs for the product must be included on each page of the catalog that lists the product. The required disclosures and all claims concerning energy consumption made in writing or in broadcast advertisements must be based on the results of test procedures developed by the Department of Energy, which are referenced in the rule.

Section 305.8(b) of the rule requires manufacturers, after filing an initial report, to report annually by specified dates for each product type.[3] Because the costs for the various types of energy change yearly, and because manufacturers regularly add new models to their lines, improve existing models and drop others, the data base from which the ranges of comparability are calculated is constantly changing.

To keep the required information in line with these changes, the Commission is empowered, under section 305.10 of the rule, to publish new ranges (but not more often than annually) if an analysis of the new data indicates that the upper or lower limits of the ranges have changed by more than 15%.

The new figures for the estimated annual costs of operation for refrigerators, refrigerator-freezers, and freezers, which were calculated using the 1992 representative average energy cost for electricity (8.25 cents per kilowatt-hour) published by DOE on January 14, 1992,[4] have been submitted and have been analyzed by the Commission. New ranges based upon them are herewith published.

In consideration of the foregoing, the Commission amends Appendices A–1, A–2 and B of its Appliance Labeling Rule by publishing the following ranges of comparability for use in the labeling and advertising of refrigerators, refrigerator-freezers, and freezers beginning April 8, 1993.

List of Subjects in 16 CFR Part 305

Advertising, Energy conservation, Household appliances, Labeling, Reporting and recordkeeping requirements.

Accordingly, 16 CFR part 305 is amended as follows:

PART 305—[AMENDED]

1. The authority citation for part 305 continues to read as follows:

Authority: Sec. 324 of the Energy Policy and Conservation Act (Pub. L. 94–163) (1975), as amended by the National Energy Conservation Policy Act, (Pub. L. 95–619) (1978), the National Appliance Energy Conservation Act, (Pub. L. 100–12) (1987), and the National Appliance Energy Conservation Amendments of 1988, (Pub. L. 100–357)(1988), 42 U.S.C. 6294; sec. 553 of the Administrative Procedure Act, 5 U.S.C. 553.

2. In Appendices A1, A2 and B, Paragraph 1 of each and the introductory text in Paragraph 2 of each are revised to read as follows:

Appendix A1 to Part 305—Refrigerators

1. Range Information:

Manufacturer's rated total refrigerated volume in cubic feet	Ranges of estimated yearly energy costs	
	Low	High
Less than 2.5	$23	$30
2.5 to 4.4	5	35
4.5 to 6.4	23	51
6.5 to 8.4	34	37
8.5 to 10.4	9	39
10.5 to 12.4	40	41
12.5 to 14.4	40	46
14.5 to 16.4	19	19
16.5 and over	36	59

2. Yearly Cost Information: Estimates on the scale are based on a national average electric rate of 8.25¢ per kilowatt hour.

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Appendix A2 to Part 305—Refrigerators-Freezers

1. Range Information:

Manufacturer's rated total refrigerated volume in cubic feet	Ranges of estimated yearly energy costs	
	Low	High
Less than 10.5	$17	$59
10.5 to 12.4	55	79
12.5 to 14.4	25	71
14.5 to 16.4	31	72
16.5 to 18.4	47	86
18.5 to 20.4	57	106
20.5 to 22.4	60	108
22.5 to 24.4	64	121

[1] 44 FR 66466, 16 CFR Part 305.

[2] Pub. L. 94–163, 89 Stat. 871 (Dec. 22, 1975).

[3] Reports for refrigerators, refrigerator-freezers and freezers are due by August 1.

[4] 57 FR 1461. The Commission published these figures on February 20, 1992, at 57 FR 6071.

Manufacturer's rated total refrigerated volume in cubic feet	Ranges of estimated yearly energy costs	
	Low	High
24.5 to 26.4	77	125
26.5 to 28.4	102	128
28.5 and over	109	133

[1] No data submitted.

2. Yearly Cost Information: Estimates on the scale are based on a national average electric rate of 8.25¢ per kilowatt hour.

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Appendix B to Part 305—Freezers

1. Range Information:

Manufacturer's rated total refrigerated volume in cubic feet	Ranges of estimated yearly energy costs	
	Low	High
Less than 5.5	$14	$53
5.5 to 7.4	28	45
7.5 to 9.4	26	46
9.5 to 11.4	30	58
11.5 to 13.4	33	80
13.5 to 15.4	36	82
15.5 to 17.4	48	69
17.5 to 19.4	50	92
19.5 to 21.4	52	89
21.5 to 23.4	46	59
23.5 to 25.4	(*)	(*)
25.5 to 27.4	53	65
27.5 to 29.4	(*)	(*)
29.5 and over	139	222

2. Yearly Cost Information: Estimates on the scale are based on a national average electric rate of 8.25¢ per kilowatt hour.

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By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 93–118 Filed 1–7–93; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 89C–0430]

Listing of Color Additives For Coloring Contact Lenses; Vinyl Alcohol/Methyl Methacrylate-C.I. Reactive Red 180 Reaction Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use in coloring contact lenses of the reaction product formed by chemically bonding the dye C.I. Reactive Red 180 [5-(benzoylamino)-4-hydroxy-3-((1-sulfo-6-((2-(sulfooxy)ethyl) sulfonyl)-2-naphthalenyl)azo)-2,7-naphthalenedisulfonic acid, tetrasodium salt] (CAS Reg. No. 98114–32–0) to the vinyl alcohol/methyl methacrylate copolymeric lens material. This action is in response to a petition filed by Ciba Vision Corp.

DATES: Effective February 9, 1993, except as to any provisions that may be stayed by the filing of proper objections; written objections by February 8, 1993.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9511.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of December 19, 1989 (54 FR 51945), FDA announced that a color additive petition (CAP 9C0217) had been filed by Ciba Vision Corp., P.O. Box 105069, Atlanta, GA 30348. The petition proposed that the color additive regulations be amended to provide for the safe use of six vinyl sulfone reactive dyes to color contact lenses prepared from a copolymer that is the reaction product of the dye and a polyvinyl alcohol/methyl methacrylate copolymer. The dyes are as follows:

(1) C.I. Reactive Black 5 (2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-3,6-bis((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-, tetrasodium salt], CAS Reg. No. 17095–24–8);

(2) C.I. Reactive Blue 21 (copper, (29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32)-,sulfo((4-((2-(sulfooxy) ethyl)sulfonyl)phenyl)amino)sulfonyl derivatives, CAS Reg. No. 73049–92–0);

(3) C.I. Reactive Orange 78 (2-naphthalenesulfonic acid, 7-(acetylamino)-4-hydroxy-3-((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-, CAS Reg. No. 68189–39–9);

(4) C.I. Reactive Yellow 15 (benzenesulfonic acid, 4-(4,5-dihydro-4-((2-methoxy-5-methyl-4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-3-methyl-5-oxo-1H-pyrazol-1-yl)-, CAS Reg. No. 60958–41–0);

(5) C.I. Reactive Blue No. 19 (2-anthracenesulfonic acid, 1-amino-9,10-dihydro-9,10-dioxo-4-((3-((2-(sulfooxy)ethyl)sulfonyl)phenyl)amino)-, disodium salt, CAS Reg. No. 2580–78–1); and

(6) C.I. Reactive Red 180 (5-(benzoylamino)-4-hydroxy-3-((1-sulfo-6-((2-(sulfooxy)ethyl)sulfonyl)-2-naphthalenyl)azo)-2,7-naphthalenedisulfonic acid, tetrasodium salt, CAS Reg. No. 98114–32–0).

Ciba Vision Corp. has changed its address to 11460 Johns Creek Pkwy., Duluth, GA 30136–1518.

The petitioner has also requested that, at this time, the agency regulate separately the color additive formed by the reaction of C.I. Reactive Red 180 with vinyl alcohol/methyl methacrylate copolymer. The safety of the other five vinyl alcohol/methyl methacrylate-dye reaction products is still under review, and the agency's decision with regard to regulation of these color additives will be addressed in a later **Federal Register** document. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

II. Applicability of The Act

With the passage of the Medical Device Amendments of 1976 (Pub. L. 94–295), Congress mandated the listing of color additives for use in medical devices when the color additive comes in direct contact with the body for a significant period of time (21 U.S.C. 376(a)). The use of the vinyl alcohol/methyl methacrylate-C.I. Reactive Red 180 reaction product as a color additive in contact lenses is subject to this listing requirement. The color additive is added to contact lenses in such a way that at least some of the color additive will come in contact with the eye when the lenses are worn. In addition, the lenses are intended to be placed on the eye for several hours a day, each day, for 1 year or more. Thus, the color additive will be in direct contact with the body for a significant period of time. Consequently, the use of the color additive currently before the agency is subject to the statutory listing requirement.

III. Identity

The color additive is the reaction product of the reactive dye C.I. Reactive Red 180 [5-(benzoylamino)-4-hydroxy-3-((1-sulfo-6-((2-(sulfooxy)ethyl)sulfonyl)-2-naphthalenyl)azo)-2,7-naphthalenedisulfonic acid, tetrasodium salt] (CAS Reg. No. 98114–32–0) and the vinyl alcohol/methyl methacrylate copolymer. The dye is reacted with contact lenses fabricated from the vinyl alcohol/methyl methacrylate copolymer. During the reaction, the sulfate groups

of the dye are replaced by ether linkages to the copolymeric lens material. As a result, a thin layer of colored copolymeric material forms on the surface of the lenses and colors the contact lenses. As part of the manufacturing process, the lenses are thoroughly washed to remove unbound dye.

IV. Safety Evaluation

The agency believes that because the reactive dye C.I. Reactive Red 180 has a significantly lower molecular weight than the vinyl alcohol/methyl methacrylate-dye copolymer, it would be more readily absorbed into the body than the copolymeric color additive and would thus be expected to show a greater toxic effect. Therefore, the safety evaluation of the subject color additive focused primarily on C.I. Reactive Red 180.

FDA concludes from the data submitted in the petition and from other relevant information that the exposure to C.I. Reactive Red 180 from its use to produce the color additive in the contact lenses is 3.3 nanograms (ng) per person per day. The exposure calculated by the agency was based on two factors. First, from extraction studies conducted by the petitioner on contact lenses colored with the vinyl alcohol/methyl methacrylate-C.I. Reactive Red 180 reaction product, the agency has determined that the amount of dye that could migrate from the colored contact lenses is no more than 0.6 micrograms (μg) per lens. Secondly, the agency made two worst-case assumptions that: (1) A user will replace lenses colored with the vinyl alcohol/methyl methacrylate-C.I. Reactive Red 180 reaction product once each year with a new pair of lenses tinted with the same color additive; and (2) 100 percent of the extractible reactive dye will migrate from the lenses into the eyes over the 1-year period. Because these assumptions are worst-case estimates, exposure to C.I. Reactive Red 180 from its use to produce the color additive in contact lenses is likely to be less than 3.3 ng per person per day (Ref. 1).

In evaluating the safety of the reactive dye C.I. Reactive Red 180, the agency considered two in-vitro cytotoxicity studies contained in its files on C.I. Reactive Red 180 by the direct-contact method. From these studies, the maximum noncytotoxic concentration for the reactive dye was determined to be 10 μg per milliliter (mL) using mouse fibroblast cells. In addition, the petitioner conducted toxicity tests to establish that the vinyl alcohol/methyl methacrylate-C.I. Reactive Red 180 reaction product is safe for use in coloring contact lenses. These tests included in-vitro cytotoxicity studies on the lenses and on lens extracts using mouse fibroblast cells and the agar-overlay method. The petitioner also conducted an acute systemic toxicity test on mice using lens extracts and 21-day ocular irritation studies on rabbits using the colored lenses. The above referenced studies demonstrated no evidence of cytotoxicity, acute systemic toxicity, or ocular irritation.

To relate the no-effect level of 10 μg/mL, established in the direct-contact cytotoxicity studies on C.I. Reactive Red 180, to the 3.3 ng per person per day exposure from wearing the colored lenses, the agency calculated the maximum concentration level of reactive dye in each eye that would result from the use of the contact lens. The agency estimated that the daily exposure to reactive dye in each eye would be 1.65 ng and that this would be diluted by the average daily tear film of 1.2 mL produced in each eye. This concentration is equal to a maximum daily concentration in the tear flow of the eye of 1.38 ng/mL. When this concentration is compared with the no-effect level of 10 μg/mL, this represents a 7,300-fold safety factor for this proposed use of C.I. Reactive Red 180.

Based upon the available toxicity data, the small amount of vinyl alcohol/methyl methacrylate-C.I. Reactive Red 180 reaction product in the contact lenses, and the agency's exposure calculation, FDA finds that the reaction product formed by chemically bonding the dye C.I. Reactive Red 180 to vinyl alcohol/methyl methacrylate copolymer is safe for use as a color additive in contact lenses. FDA further concludes that the use of the color additive shall not exceed the minimum amount reasonably expected to accomplish the intended coloring effect. Batch certification is not required to ensure safety.

V. Conclusions

Based on data contained in the petition and other relevant information, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of vinyl alcohol/methyl methacrylate-C.I. Reactive Red 180 reaction product as a color additive in contact lenses, and that the additive is safe and suitable for the intended use. Therefore, the agency is amending the regulations by adding new § 73.3127.

VI. Inspection of Documents

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition (address above) by appointment with the information contact person listed above. As provided in § 71.15, the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VII. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Food and Color Additives Review Section to the Indirect Additives Branch, "CAP's 8C0212 and 9C0217 - Ciba Vision Corp. Remazol Red 180 for Use in Colored Contact Lenses. Validation of Limit of Detection. Submission dated 7–8–91," February 24, 1992.

IX. Objections

Any person who will be adversely affected by this regulation may at any time on or before February 8, 1993, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the

objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: Secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 376).

2. New § 73.3127 is added to subpart D to read as follows:

§ 73.3127 Vinyl alcohol/methyl methacrylate-dye reaction products.

(a) *Identity.* The color additive is formed by reacting a dye with a vinyl alcohol/methyl methacrylate copolymer, so that the sulfate groups of the dye are replaced by ether linkages to the vinyl alcohol/methyl methacrylate copolymer. The dye is: C.I. Reactive Red 180 [5-(benzoylamino)-4-hydroxy-3- [(1-sulfo-6-[(2-(sulfooxy)ethyl]sulfonyl)-2-naphthalenyl]azo)- 2,7-naphthalenedisulfonic acid, tetrasodium salt] (CAS Reg. No. 98114–32–0).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used to color contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) As part of the manufacturing process, the lenses containing the color additive are thoroughly washed to remove unbound reactive dye.

(3) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act). A person intending to introduce a device containing a vinyl alcohol/methyl methacrylate-dye reaction product listed under this section into commerce shall submit to the Food and Drug Administration either a premarket notification in accordance with subpart E of part 807 of this chapter, if the device is not subject to premarket approval, or submit and receive approval of an original or supplemental premarket approval application if the device is subject to premarket approval.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore, this color additive is exempt from the certification requirements of section 706(c) of the act.

Dated: December 31, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–317 Filed 1–7–93; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 888

[Docket No. 89P–0387]

Medical Devices; Reclassification and Codification of Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the reclassification and codification of the hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. FDA issued an order in the form of a letter to two manufacturers reclassifying the device from class III into class II. Accordingly, FDA is amending the regulations as set forth below.

DATES: The reclassification was effective February 21, 1992. This final rule becomes effective February 8, 1993.

FOR FURTHER INFORMATION CONTACT: Nirmal K. Mishra, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301–427–1036.

SUPPLEMENTARY INFORMATION: On September 12, 1989, FDA filed a reclassification petition submitted by Richards Medical Co. (Richards) and Intermedics Orthopedics, Inc. (Intermedics), requesting reclassification of the hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis from class III into class II. FDA consulted with the Orthopedic and Rehabilitation Devices Panel (the Panel). During an open public meeting on September 22, 1989, the Panel recommended that FDA reclassify the hip joint metal/polymer/metal semi-constrained porous-coated prosthesis from class III into class II and that FDA assign a low priority for the establishment of a performance standard for the generic type of device under section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d).

FDA fully considered the Panel's recommendations and tentatively agreed that the generic type of device should be reclassified from class III into class II and that the promulgation of a performance standard for the device should be a low priority.

The Safe Medical Devices Act of 1990 (the SMDA) amended the act to change the definition of a class II device. Under the SMDA, class II devices are those devices for which there is insufficient information to show that general controls themselves will ensure safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of a performance standard. Thus, the definition of a class II device was changed from "performance standards" to "special controls." FDA's final determination was made under the standard set forth in the SMDA.

It is the agency's position that the SMDA does not require the agency to obtain new reclassification recommendations from a panel which had recommended reclassification under the previous standards. The Panel recommended the hip joint metal/polymer/metal semi-constrained porous coated prosthesis be reclassified from class III (premarket approval) into class II (performance standards). Under the SMDA, FDA may establish a performance standard, as well as establish other special controls, including postmarket surveillance, patient registries, guidelines, and other appropriate actions it believes necessary to provide reasonable assurance of the safety and effectiveness of the device.

In the Federal Register of July 15, 1991 (56 FR 32145), FDA published a notice of the Panel's recommendations and invited public comment. FDA received eight comments regarding the reclassification proposal for the generic type of device. All of the comments supported reclassification, although six of them expressed concern about various aspects of the device description, e.g., the materials, pore morphology, and specifications. Each comment was addressed in the order, which is available for examination in the Docket Management Branch (HFA–