Guidance for Industry and FDA Staff

Revised Procedures for Adding Lens Finishing Laboratories to Approved Premarket Approval Applications for Class III Rigid Gas Permeable Contact Lenses for Extended Wear

Document issued on: August 11, 1998

This document supersedes document, "New Procedures for Adding Lens Finishing Laboratories Through Supplements to Approved Premarket Approval Applications for Rigid Gas Permeable Contact Lenses," May 9, 1985

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Vitreoretinal and Extraocular Devices Branch
Division of Ophthalmic Devices
Office of Device Evaluation

GRZAN

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to James F. Saviola, O.D., Vitreoretinal and Extraocular Devices Branch (HFZ-460), Division of Ophthalmic Devices, Office of Device Evaluation, Center for Devices and Radiological Health, 9200 Corporate Blvd., Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact James F. Saviola, O.D., at 301-594-1744 or by electronic mail at JZS@cdrh.fda.gov.

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World Wide Web CDRH home page: http://www.fda.gov/cdrh or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1249 when prompted for the document shelf number.

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This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

TO: All Class III Rigid Gas Permeable Contact Lens PMA Holders and Interested Persons

SUBJECT: Revised Procedures for Adding Lens Finishing Laboratories to Approved Premarket Approval Applications for Class III Rigid Gas Permeable Contact Lenses for Extended Wear

Introduction:

On May 9, 1985, the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) issued a document entitled "New Procedures For Adding Lens Finishing Laboratories Through Supplements to Approved Premarket Approval Applications For Rigid Gas Permeable Contact Lenses." These procedures allowed small, independent contact lens finishing laboratories (hereafter referred to as lens finishing laboratories) to manufacture and distribute rigid gas permeable (RGP) contact lenses under another firm's approved premarket approval application (PMA) for an RGP contact lens, using the same material and design, for the same indications for use, and under the same labeling as the lens covered by the approved PMA. In addition, the procedures provided for manufacturers with approved PMAs for RGP contact lenses to submit 30-day supplements for additional lens finishing laboratories as manufacturers and distributors of approved lenses. The procedures stated that the PMA supplements will be deemed approved 30 days after filing if all requirements in the document were met and the PMA supplements were administratively complete.

In accordance with 21 CFR 814.39 and as part of our re-engineering efforts in PMA review, FDA is revising the May 9, 1985 policy. Under the revised policy, PMA holders may include additional finishing laboratories as manufacturers and distributors of approved RGP lenses after a protocol is approved, without submitting PMA supplements, provided the PMA holder agrees to:

1. provide the documentation listed under the heading "Documentation, Annual Reports" in its future annual reports; and

2. include the information listed under the heading "Documentation, Device Master Records and Complaint Files" in the device master records and complaint files to be made available to FDA upon request.

FDA believes that this revision can be implemented without compromising public health and safety and that it will reduce the regulatory burden on manufacturers. The procedures are consistent with procedures for adding finishing laboratories for manufacturing and distributing class II contact lenses, which are included in the May 12, 1994, guidance entitled "PREMARKET NOTIFICATION (510(k)) GUIDANCE DOCUMENT FOR DAILY WEAR CONTACT LENSES."

NOTE: THIS PROCEDURE REPLACES THE MAY 9, 1985, POLICY ENTITLED "NEW PROCEDURES FOR ADDING LENS FINISHING LABORATORIES THROUGH SUPPLEMENTS TO APPROVED PREMARKET APPROVAL APPLICATIONS FOR RIGID GAS PERMEABLE CONTACT LENSES." PLEASE NOTE THAT THIS PROCEDURE APPLIES TO CLASS III RGP CONTACT LENSES ONLY; IT DOES NOT APPLY TO SOFT (HYDROPHILIC) CONTACT LENSES.

Objectives:

Manufacturer's Objective: To obtain marketing approval for acceptable procedures to allow one or more independent finishing laboratories to manufacture and distribute finished RGP contact lenses made from lens blanks supplied by a manufacturer with a previously approved PMA.

FDA's Objective: To ensure that lenses finished by independent laboratories will conform to the specifications of approved PMA or PMA supplements, to ensure safe and effective RGP contact lenses, and to ensure that finishing laboratories will comply with all PMA post-approval requirements.

Responsibilities:

FDA considers the finishing of RGP contact lenses by lens finishing laboratories to be an extension of the manufacturing process for RGP contact lenses. The PMA holder is ultimately responsible for assuring that each finishing laboratory produces lenses that are essentially identical to the approved lens and that all quality assurance activities necessary to determine that finished contact lenses meet specifications are appropriate, adequate, and correctly performed. Each independent finishing laboratory is responsible for complying with those parts of the device Good Manufacturing Practice Requirements, as set forth in the Quality System Regulation for medical devices, which apply to the manufacturing operations that the finishing laboratory performs for the PMA holder.

Requirements:

The PMA holder must receive FDA approval of a PMA or PMA supplement that contains a protocol for adding additional finishing laboratories as manufactures and distributors of RGP lenses before implementing the procedures in this document. PMA holders with currently approved protocols are not required to resubmit new protocols.

An approved contact lens PMA provides evidence that a lens material is not toxic, that the lens can be cleaned and disinfected satisfactorily, that it can be manufactured according to specifications and in compliance with Good Manufacturing Requirements, as set forth in the Quality System Regulation for medical devices; and that it is clinically safe and effective for its labeled indications. These procedures specify the conditions under which independent finishing laboratories may be included under an approved PMA or PMA supplement for class III RGP contact lenses.

The information that should be submitted to FDA in a PMA or PMA supplement to obtain approval of a protocol for adding additional finishing laboratories includes:

1. the information that the PMA holder plans to provide to the lens finishing laboratories pertaining to finishing the approved RGP lens (should be the same information as in the approved PMA); and

2. the monitoring plan, and other information specified below which the PMA holder will use to evaluate the lens finishing laboratories to qualify them as manufacturers and distributors of the approved RGP lens.

The approved protocol and monitoring plan for continued surveillance over each finishing laboratory provide FDA with assurance of the PMA holder's ability to evaluate lens finishing laboratories in accordance with approved specifications. The PMA approval, along with documentation in the next annual report of the PMA holder's evaluation of each lens finishing laboratory's ability to manufacture the RGP lens to approved specifications, provide FDA with reasonable assurance that approved finishing laboratories can manufacture lenses that are essentially identical to those approved in the PMA. Allowing PMA holders to qualify lens finishing laboratories and provide documentation in the next annual report eliminates the requirement of obtaining explicit FDA approval of a PMA supplement for adding additional finishing laboratories as manufacturers and distributors of approved RGP lenses, when the documentation listed on pages 7 and 8 are included in the PMA owners device master records and complaint files.

Consequently, FDA has concluded that a contact lens finishing laboratory that is (a) evaluated by a manufacturer holding an approved PMA for an RGP contact lens, in accordance with a protocol approved by FDA in the same PMA or in a PMA supplement, and (b) found by the PMA holder to meet all the requirements specified in this document, may begin manufacturing, selling, and shipping the lens that is the subject of the approved PMA, in accordance with the conditions of approval of the approved PMA, after the PMA holder has documented conformance with the information specified in this document in the firm's device master records and complaint files.

Listed below are nine key quality assurance activities that FDA requires the laboratories to perform as well as instructions to PMA holders for designing a protocol for the evaluation of a laboratory's ability to manufacture the lenses and meet the quality assurance requirements. The information that should be provided to the lens finishing laboratories includes, but is not limited to, the following:

1. Complete range of specifications for the contact lenses, and detailed process instructions for any manufacturing steps that require processing in a manner that is in any way unique to the material from which the lenses are to be manufactured.

2. Complete and accurate copies of all the labeling for distribution with the lens, as approved by FDA in the PMA, including the cautionary statement, "Caution: Non-sterile. Clean and condition lenses prior to use."

3. A detailed description of the following key quality assurance activities that lens finishing laboratories are required to perform:

    a) incoming material specifications;

    b) acceptance/rejection criteria at each manufacturing step;

    c) identity and specifications for each processing compound, such as sealing waxes and polishing compounds;

    d) cleaning instructions and specifications for cleaning compounds;

    e) final product acceptance criteria and test methods;

    f) identity and specification for packaging and labeling materials;

    g) disinfection instructions (or sterilization instructions if labeled as sterile) in accordance with the approved PMA, process validation, and product release procedures [please refer to the section entitled "Microbiology Requirements for Hydrophobic Contact Lenses," of the document entitled "PREMARKET NOTIFICATION (510(k)) GUIDANCE DOCUMENT FOR DAILY WEAR CONTACT LENSES" for guidance] ;

    h) records maintenance including device history records sufficient to ensure the traceability of any lens to the lot or batch of material; as identified by the material supplier, from which the lens was manufactured, and complete complaint files;

i) continuing quality audit procedures to be employed by the lens finishing laboratories' personnel in accordance with the definition in the current Good Manufacturing Requirements, as set forth in the Quality System Regulation for medical devices, 21 CFR 820.3(t), which states:

"Q*uality audit* means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives."

To obtain approval of a protocol for adding lens finishing laboratories as manufacturers and distributors of approved RGP lenses, the PMA holder must obtain approval of a PMA or PMA supplement containing the following information for evaluation of the lens finishing laboratories, and must ensure compliance with the conditions of approval of the PMA:

1. The information provided to lens finishing laboratories, as listed above.

2. A satisfactory protocol for a presubmission evaluation of the laboratory. This evaluation may include (a) an on-site inspection or (b) a questionnaire to be answered by the laboratory and reviewed by the PMA holder. If the laboratory did not participate in clinical trials on the lens that is subject to the PMA holder's application, the protocol should require that each finishing laboratory prepare at least 10 lenses from at least 10 different prescriptions provided by the PMA holder, who will inspect the lenses to determine whether they meet the final product criteria of the lenses covered by the approved PMA. The protocol should be approved by FDA before it is used to evaluate laboratories to ensure that FDA will accept the inspection results. The protocol should include procedures whereby the PMA holder will verify that each lens finishing laboratory is in compliance with the sponsor's standard operating procedures and FDA's Good Manufacturing Requirements, as set forth in the Quality System Regulation for medical devices, and that finished lenses sampled in accordance with the inspection sampling plan comply with the PMA holder's approved lens specifications with respect to design, labeling dimensions, powers, surface finish, edge finish, and sterility.

3. A monitoring plan for continued surveillance over each finishing laboratory to monitor audit procedures and ensure continued conformance of lenses to the approved specifications.

4. A plan for an adverse reaction reporting system to be established and maintained by the PMA holder, encompassing all approved finishing laboratories and meeting all provisions of the "Adverse Reaction and Device Defect Reporting" and the "Reporting Under the Medical Device Reporting (MDR) Regulations" section of the "Conditions of Approval" for PMAs, dated March 4, 1998 (copy attached). The lens finishing laboratories must report any adverse reactions to the PMA holder within 10 days of becoming aware of such reactions.

5. Two suitably worded sworn declarations; one declaration to be completed and signed by a responsible official from each lens finishing laboratory stating that, once the laboratory begins manufacturing the lenses, the laboratory will comply with (a) the PMA holder's approved manufacturing process, (b) all requirements of the Federal Food, Drug, and Cosmetic Act, (c) the PMA approval order, and (d) this document; and a second declaration to be completed and signed by the PMA holder verifying that the lens laboratory has been evaluated in accordance with, and found to conform to, all provisions of the protocol described in item 2, page 5.

After approval of the PMA or PMA supplement containing the documentation specified above, and after the PMA holder has documented that the lens finishing laboratories have been found to have met all evaluation criteria and the declarations described in item 5, page 6, have been signed and placed in the PMA holder's device master records, the lens finishing laboratories may begin manufacturing and distributing the approved RGP contact lenses.

Documentation:

After obtaining approval for a PMA or PMA supplement containing a protocol for additional finishing laboratories, the PMA holder may provide for additional finishing laboratories to manufacture and distribute the approved RGP lenses by following the procedures in this document and documenting the following information in the next annual report to FDA and the firm's device master records and complaint files to be made available to FDA upon request:

1. Annual Report

   a) Copy of the PMA holder's agreement to comply with the procedures in this document.

   b) The PMA or PMA supplement number that contains the approved protocol for adding additional finishing laboratories as manufactures and distributors of RGP lenses.

c) The first annual report submitted after implementation of these revised procedures should include a complete listing of names, addresses, and responsible persons for all finishing laboratories approved under each PMA. Future annual reports should include additional finishing laboratories added since the last annual report was submitted, as well as those previously approved laboratories that are no longer participating.

d) Copies of two sworn declarations (finishing laboratory and PMA holder) in accordance with item 5, page 6.

2. Device Master Records

a) Copy of the PMA holder's agreement to comply with the procedures in this document.

b) The PMA or PMA supplement number that contains the approved protocol for adding additional finishing laboratories as manufactures and distributors of RGP lenses.

c) Copies of all documentation provided to lens finishing laboratories as listed in items 1-3(a-i), pages 4 and 5.

d) Copies of the approved protocol and PMA holder's evaluation demonstrating that each lens finishing laboratory has been evaluated and found to comply with all elements in the approved protocol, as listed in item 2, page 5.

e) Copy of the monitoring plan used for continued surveillance over each finishing laboratory to monitor audit procedures and ensure continued conformance of lenses to the approved specifications, as listed in item 3, page 5, along with a record of surveillance over each laboratory

f) Copy of the PMA holder's plan for Adverse Reaction and Device Defect Reporting and Reporting Under the Medical Device Reporting (MDR) Regulations section of the "Conditions of Approval" for PMAs dated March 4, 1998, as listed in item 4, page 6. All adverse reactions associated with use of the approved RGP lens should be documented in the PMA holder's complaint files.

g) Copies of two sworn declarations (finishing laboratory and PMA holder) in accordance with item 5, page 6.

h) The names, addresses, and names and titles of persons at each finishing laboratory responsible for compliance with these procedures; the private label brand name, if applicable; date on which the addition of lens finishing laboratory was implemented; and any change in the above items.

3. Complaint Files

All complaints associated with the device, including adverse reactions described in item 2(f).

Effective Date: The above procedures are effective as of date of issuance.

If you have any questions, please contact James F. Saviola, O.D., at (301) 594-1744.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Attachment (Conditions of Approval Dated March 4, 1998)

GRZAN

GCOA
Issued: 3-4-98

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1)Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a)unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b)reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1)A mix-up of the device or its labeling with another article.

(2)Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a)has not been addressed by the device's labeling or

(b)has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3)Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

(1)May have caused or contributed to a death or serious injury; or

(2)Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., “Manufacturer Report,” “5-Day Report,” “Baseline Report,” etc. Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336)and FDA publications entitled “An Overview of the Medical Device Reporting Regulation” (FOD # 509) and “Medical Device Reporting for Manufacturers” (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH’s Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH’s Division of Small Manufacturers Assistance (DSMA) at 301-443-8818.