the sponsor first learns of the IRB’s determination.

(10) Other. A sponsor shall, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

§ 813.2 Applicability.
This part applies to all implantations of intraocular lenses in humans unless a premarket approval application has been approved for these lenses under section 515 of the act.

§ 813.3 Definitions.
(a) Intraocular lens means a lens intended to replace surgically the natural lens of the human eye. An intraocular lens is, for purposes of this part, synonymous with "investigational device," "lens," or "lenses.
(b) Investigational device means a device that is used in an investigational study involving human subjects, where the study is for the purpose of determining if the device is safe or effective.
(c) Investigational plan means a plan or protocol for using an investigational device in an investigational study. See §813.25 for requirements applicable to an investigational plan.
(d) Investigational study means a study involving human subjects when the study is for the purpose of determining if an investigational device is safe or effective and includes any implantation in a human of an intraocular lens for which there is no approved application for premarket approval under section 515 of the act.
(e) Investigator means an individual who actually conducts an investigational study, i.e., under whose immediate direction the investigational device is administered or dispensed to, or used involving, a subject.
(f) Monitor, when used as a noun, means an individual selected by a sponsor or contract research organization to oversee the progress of an investigational study. The monitor may be a full-time employee of a sponsor or contract research organization or a consultant to the sponsor or contract research organization. (Monitor, when used as a verb, means the act of reviewing the progress of an investigational study.)
(g) Sponsor means a person who initiates an investigational study, but who does not actually conduct the study (i.e., the investigational device is administered or dispensed to, or used involving, a subject under the immediate direction of another individual). A person other than an individual, e.g., corporation or government agency, that uses one or more of its own employees to conduct an investigational study that it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.
(h) Sponsor-investigator means an individual who both initiates and actually conducts, alone or with others, an investigational study (i.e., under whose immediate direction the investigational device is administered or dispensed to, or used involving, a subject). The term does not include any person other than an individual. Any sponsor-investigator shall carry out the responsibilities under this part of a sponsor and of an investigator.
(i) Institution means a person (other than an individual) who engages in the conduct of research on human subjects or in the delivery of medical services to human subjects as a primary activity or as an adjunct to providing residential or custodial care to human beings. The term includes a hospital, retirement home, prison, university, or device manufacturer. Facility as used in section 520(g) of the act is deemed to be synonymous with the term institution for purposes of this part.
(j) Subject means an individual who is or becomes a participant in an investigational study, either as a recipient of the investigational device or as a control. A subject may be either a non-patient volunteer or a patient on whom the intraocular lens might have a therapeutic effect.

(k) Person includes an individual, partnership, corporation, association, scientific establishment, government agency, and any other legal entity.

(l) Institutional review committee means a committee (appointed by an institution to review and monitor investigations in which human subjects participate) whose major responsibility is the protection of human subjects from risk to their health, safety, or dignity in accordance with the current professional standards and the requirements of this part. Such a committee may be known as an institutional review board or by other names.

§ 813.5 General qualifications for an exemption.

A shipment of an intraocular lens is exempt from any or all the otherwise applicable requirements of the act enumerated in § 813.1(b)(1) if all the following conditions are met:

(a) The label of the device bears the following: the name and place of business of the manufacturer, packer, or distributor in accordance with § 801.1 of this chapter; the quantity of contents; the sterility shelf life of the lens; and the statement, "Caution—investigational device. Limited by Federal (or United States) law to investigational use".

(b) The labeling of the intraocular lens is not false or misleading in any particular.

(c)(1) An application for investigational device exemption covering that shipment was submitted by the sponsor under Subpart B of this part, and the requisite time has elapsed following the date of receipt of the application by the Food and Drug Administration to permit the investigational study to begin under § 813.30(b).

(2) The Commissioner has not disapproved the application or withdrawn the exemption.

(d) Each shipment of the intraocular lens is made in accordance with the commitments in the application and any conditions imposed in the Commissioner's approval of the application.

(4) The sponsor has complied with the requirements of Subparts B, C, and G of this part, any institutional review committee that is to review and approve the investigational study for which shipment is made has complied with the requirements of Subparts D and G of this part, and the investigator(s) to which the shipment is to be made has complied with the requirements of Subparts E and G of this part and with the requirements for informed consent contained in Part 50 of this chapter.

(d) If the shipment is to be imported into or exported from the United States, the requirements of § 813.19 have been met.

[42 FR 58889, Nov. 11, 1977, as amended at 47 FR 46079, Oct. 15, 1982]

§ 813.10 Petitions for waiver of requirements.

(a) Any person subject to any requirement under this part may petition the Commissioner for a waiver of such requirement. Such a petition shall be submitted in accordance with § 10.30 of this chapter and shall set forth the basis for the petitioner's belief that compliance with the requirement is not necessary to achieve the objectives of this part and, where appropriate, any alternative means to achieve the objective of the requirement from which the waiver is sought.

(b) The Commissioner may, at his discretion, grant a petition for a waiver submitted under this section if he finds that compliance with the requirement from which the waiver is sought is not necessary to achieve the objectives of this part and, where appropriate, any alternative means to achieve the objective of the requirement from which the waiver is sought.

(c) The person who submits a petition under this section continues to be subject to the requirement from which the waiver is sought unless and until the Commissioner grants the petition.
§ 813.12 Information previously submitted.

Wherever this part requires the submission to the Food and Drug Administration of information or data that previously had been submitted in accordance with this part or other parts of this chapter, the information or data need not be resubmitted but may be incorporated by reference.

§ 813.19 Requirements applicable to importers and exporters of intraocular lenses.

(a) Any person who imports or offers for importation into the United States an intraocular lens shall assure that all the following requirements are met:

1. The labeling of such lens complies with §813.5 (a) and (b).
2. The importer of such shipment is an agent in the United States of the foreign exporter or is the ultimate consignee, and the foreign exporter or the ultimate consignee has, prior to such shipment, completed and submitted to the Food and Drug Administration an application for an investigational device exemption in accordance with §813.20 and acts as the sponsor of the investigational study to assure compliance with the procedures, conditions, and requirements of this part.
3. The requisite time has elapsed after the date of receipt of the application by the Food and Drug Administration to permit the investigational study to begin under §813.30(b).
4. The Commissioner has not disapproved the application or withdrawn the exemption.

(b) Any person who exports an intraocular lens from the United States to a foreign country shall comply with all the following requirements:

1. The lens shall conform to the specifications of the foreign purchaser.
2. The lens shall comply with the laws of the country to which it is being exported.
3. The label on the outside of the shipping package shall indicate that the lens is intended for export.
4. The lens shall not be sold or offered for sale in domestic commerce.
5. The person shall obtain the approval of the exportation of the lens from the country to which it is intended for export.

(b) Any person who exports an intraocular lens from the United States to a foreign country shall comply with all the following requirements:

1. The lens shall conform to the specifications of the foreign purchaser.
2. The lens shall comply with the laws of the country to which it is being exported.
3. The label on the outside of the shipping package shall indicate that the lens is intended for export.
4. The lens shall not be sold or offered for sale in domestic commerce.
5. The person shall obtain the approval of the exportation of the lens from the country to which it is intended for export.

Subpart B—Applications for Exemption for Investigational Studies Involving Human Subjects

§ 813.20 Application.

(a) The sponsor of an investigational study shall submit to the Food and Drug Administration a completed application for an investigational device exemption that has been signed by the sponsor or an authorized representative of the sponsor. Three copies of the application and any material required to accompany the application, bound and contained in volumes of reasonable size, shall be sent by registered mail or hand delivered to the Center for Devices and Radiological Health, Document Mail Center (HFZ-401), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850. Any subsequent reports, correspondence concerning an application, and supplemental application submitted under §813.39 also shall be submitted in triplicate by registered mail or hand delivered to this address. The outside wrapper of any application or supplemental application should include the statement “Application (or Supplemental Application) for Investigational Device Exemption” and the outside wrapper of any reports or correspondence should include the statement, “Regarding an Investigational Device Exemption”.

(b) An application for an investigational device exemption for an intraocular lens shall include the following information:

1. A brief statement of its intended use(s) and how it is to be administered.
2. A description of all components, ingredients, and properties and a description of the principle of operation of the device and any anticipated changes in the device that may occur in the course of the study in enough detail so that a scientist or physician familiar with the general type of lens can make a knowledgeable judgment about
the anticipated safety and effectiveness of the lens in the proposed investigational study.

(3) A description of those methods, facilities, and controls, used for the manufacture, processing, packing, and storage of the device in enough detail so that a person generally informed in that area can make a knowledgeable judgment about the safety and effectiveness of the device in the proposed investigational study.

(4) A statement of the location(s) of the study and whether an institutional review committee(s) is to monitor the study at such location(s).

(5) A report of prior investigations of the device that meets the requirements of §813.27 and a summary of the investigational plan.

(6)(i) A statement from the sponsor that an investigational plan that meets the requirements of §813.25 and a report of prior investigations of the device that meets the requirements of §813.27 have been submitted to and approved by the institutional review committee, or (ii) if no institutional review committee exists and one cannot be formed, a statement from the head of the institution that such a committee cannot be formed, and copies of the investigational plan and the report of prior investigations.

(7) A statement from any institutional review committee (where a committee is to monitor the study), signed by the chairman, that the committee has approved the investigational plan and has reviewed the report of prior investigations of the lens, that the committee will review the study periodically at intervals appropriate to the degree of risk but not to exceed 1 year, and that it will review reports of unexpected adverse effects on a timely basis for the purpose of determining if the study should be continued.

(8) A copy of all informational materials to be given to subjects, including all form(s) to be used to obtain informed consent of human subjects as required by Part 50 of this chapter (this material may be appended to the investigational plan or the summary of the investigational plan).

(9) A copy of all informational material, including labels and other labeling, which is to be supplied to investigators as required by §813.47(a).

(10) A description of the scientific training and experience that the sponsor considers appropriate to qualify individuals as suitable experts to investigate the safety and effectiveness of the intraocular lens. (See §813.43(a).)

(11) A copy of the agreement signed by investigators who will be participating, to comply with Subparts E and G of this part and Part 50 of this chapter as required by §813.43(b).

(12) The name and a summary of the training and experience of the individual who is to monitor the progress of the study for the sponsor as required by Subpart C.

(13) A statement as to whether any institutional review committee has ever disapproved any investigational study of the device and the reasons for such disapproval.

(14) A statement that the sponsor will comply with each of the requirements of Subparts C and G of this part.

(15) A statement by a sponsor notifying FDA if he intends to charge investigators and subjects for the device.

(16) A statement by the sponsor of his reasons for any request for a waiver of the requirement of §813.30(a) that a study shall not begin before the expiration of 30 days after the Food and Drug Administration has received an application meeting the requirements of this subpart, if such waiver is requested.

(17) A claim for categorical exclusion under §25.24 of this chapter or an environmental assessment under §25.31 of this chapter.

(18) Any other information relevant to review of the application required by the Food and Drug Administration to be submitted. The sponsor may refuse to provide the information requested under paragraph (b)(18) of this section and treat FDA's request as a final disapproval for purposes of requesting a regulatory hearing under §813.30. If a sponsor fails to respond to a request for information within the time prescribed in a request, FDA may treat the application as withdrawn.

§ 813.25 Investigational plan.

(a) The investigational plan for the investigational study of an intraocular lens shall include the following:

(1) A statement of the intended use of the lens;
(2) A general outline of the plan and any anticipated or foreseeable changes or variations in the plan that may be made based on experience gained in the study;
(3) A description of what results are expected from the investigational study;
(4) A justification for beginning the study, taking into account prior experience with the intraocular lens;
(5) the expected duration of the investigational study;
(6) Identification of the investigator or investigators, the facilities where the study will occur, and any institutional review committees that will supervise the study;
(7) The patient population in which the lens will be used (in terms of age, sex, and condition) and the size of each population;
(8) A justification for using such patient population and of the size of each population;
(9) The sponsor's plan for monitoring the study in accordance with §813.46;
(10) A description of records to be maintained, and the reports to be made, by the investigator(s) and the sponsor to assure compliance with the plan and enable the progress of the investigation and the safety and effectiveness of the lenses to be reviewed by the sponsor, any institutional review committee, and the Food and Drug Administration;
(11) The plan for obtaining informed consent from subjects and copies of all informational materials to be given to subjects, including all forms and materials to be used in obtaining such consent; and
(12) A description of the scientific training and experience the sponsor considers appropriate to qualify individuals as suitable experts to investigate the safety and effectiveness of the intraocular lens. (See §813.43(a)).

(b) The procedures and conditions in the investigational plan may vary depending on the following:

(1) The scope and duration of the investigational study;
(2) The number of human subjects who are to be involved in the study;
(3) The need to permit changes to be made in the device during the study conducted in accordance with the plan; and
(4) The purpose of the study, e.g., whether the study is designed for developing data to obtain approval for the commercial distribution of the device.

(c) When an investigational study is to develop data to obtain approval for commercial distribution of the device, the Food and Drug Administration will not ordinarily regard an investigational plan as capable of providing data that will support an application for such approval unless it provides for more than one independent qualified investigator.

(d) The investigational plan may provide for additional animal tests to be made during the investigational study.


§ 813.27 Report of prior experience with the lens.

(a) A report of prior investigations with the lens shall be submitted to an institutional review committee and to the Food and Drug Administration.

(b) The report of prior investigations of a lens shall include:

(1) A bibliography of any publications relevant to the investigational study and copies of significant publications both adverse and supporting.
(2) Any other unpublished information available to the sponsor, both adverse and supporting, information relating to preclinical investigations of the lens, including appropriate tests in animals and tests in vitro, and prior clinical investigations of the device or clinical experience with the device from commercial marketing, whether in the United States or in foreign countries, in sufficient detail so that a scientist or physician familiar with the general type of lens can make a knowledgeable judgment about the anticipated safety and effectiveness of the device in the proposed investigational study.
(c) Prior investigations of a lens shall not be considered adequate to justify an investigational study involving human subjects unless the conditions of the prior investigations of the lens are comparable to the conditions of the proposed investigational study.

§ 813.30 Food and Drug Administration review of and action on an application.

(a) Upon receipt of an application for an investigational device exemption submitted in accordance with this subpart, the Food and Drug Administration will notify the sponsor of the date of such receipt and inform the sponsor that the investigational study may not be begun until 30 days after the date of the agency’s receipt of the application, unless the agency has decided to waive the 30-day time requirement and so informs the sponsor.

(b) An application for an investigational device exemption shall be deemed to be approved on the 30th day after the Food and Drug Administration received the application unless, on or before such day, the Commissioner finds that the application does not meet the requirements of this part and by order disapproves the application, stating his reasons therefor, or finds the application deficient and requests additional information or suggests revisions, or approves the application with modifications. If the Commissioner requests additional information or suggests revisions, the sponsor may treat the application as disapproved for purposes of requesting a regulatory hearing under Part 16 of this chapter.

(c) The Commissioner may by order disapprove an application if he makes any of the following findings:

(1) The application contains an untrue statement of a material fact or omits material information required by §813.20.

(2) The report of prior investigations of the intraocular lens is inadequate to support a conclusion that it is reasonably safe to begin or continue the proposed investigational study.

(3) There is reason to believe that the lens may be unsafe or ineffective when used for the purpose or in the manner for which it is to be investigated.

(4) The investigational plan described in the application is not a reasonable plan, in whole or in part, for a scientific investigation to determine whether the investigational device is safe or effective.

(5) The methods, facilities, and controls used for the manufacturing, processing, packing, storage, or implantation of the lens do not assure adequately the safety and effectiveness of the lens.

(6) The sponsor’s proposed use of the lens is not intended solely for an investigational study, since it is being or is to be sold or otherwise commercially distributed in a manner not justified by the requirements of the investigational study and not permitted by this part.

(7) The proposed investigational study on which the application is submitted does not conform to procedures, conditions, or requirements prescribed in this part.

(8) The proposed investigational study subjects human subjects to undue risks. In assessing risks, the Commissioner shall consider, among other things, the factors prescribed in §813.66(f).

(d) The Commissioner shall notify the sponsor of an approval, disapproval, or approval with modifications of an application. The notification shall contain the order of the approval, disapproval, or approval with modifications and a complete statement of the reasons for the order. An order that is a notification of disapproval or approval with modifications shall advise the sponsor that he has recourse to an opportunity for a regulatory hearing pursuant to Part 16 of this chapter.

(e) The Commissioner may in his discretion decide not to disapprove an application for which there are grounds for disapproval if he concludes that risks do not outweigh the benefits to subjects.

§ 813.35 Withdrawal of an exemption.

(a) The Commissioner may by order withdraw an exemption granted under this part if he makes any of the following findings:

(1) The application for such exemption or any subsequent report contains
§ 813.38 Confidentiality of data and information in an application.

(a) The existence of an application for an investigational device exemption will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in the Food and Drug Administration file concerning the application shall be handled in accordance with the provisions established in §814.9.

(c) Notwithstanding the provisions of §814.9 of this chapter, the Food and Drug Administration shall disclose upon request to an individual in whom an intraocular lens has been used a copy of any adverse reaction report relating to such use.

(d) An exemption that has been withdrawn under section may be reinstated if the sponsor satisfies the Commissioner that the grounds for withdrawal no longer apply.

[42 FR 58889, Nov. 11, 1977, as amended at 53 FR 11253, Apr. 6, 1988]
§ 813.39 Supplemental applications and submissions concerning applications.

(a) Except as provided in paragraphs (b), (c), and (d) of this section, information contained in an application submitted under § 813.20 may be updated by means of a report to the Food and Drug Administration under § 813.153.

(b)(1) Whenever the sponsor or any investigator participating in an investigational study wishes to implement a change in, or deviation from, the investigational plan submitted to the Food and Drug Administration under § 813.20 that may affect the validity of the study or the rights or safety of the human subjects under the criteria in paragraph (b)(3) of this section, the sponsor shall submit to the Food and Drug Administration a supplemental application describing the proposed change or deviation and the justification therefor. Except as provided in paragraph (b)(2) of this section, the sponsor shall submit the supplemental application before the change or deviation is implemented, shall obtain the prior review and approval of any institutional review committee pursuant to §§ 813.42(d) and 813.105, shall attach to such supplemental application a copy of the approval of such change or deviation by such committee, and shall not permit the change or deviation to be implemented unless and until the supplemental application is approved or deemed approved under § 813.30(b), except as described in paragraph (b)(2) of this section.

(2) When a change or deviation is necessary to eliminate or reduce an apparent immediate hazard to the safety of a human subject who is already participating in the investigational study, the sponsor is not required to comply with the prior approval requirements of paragraph (b)(1) of this section. The sponsor shall instead notify the Food and Drug Administration and any institutional review committee that is added to an investigational study after submission of an application for an investigational device exemption under § 813.20(b). Any such additional statement shall be submitted before an investigator may begin participation in the investigational study.

(d) The sponsor shall submit to the Food and Drug Administration any additional informational materials to be given to subjects, including forms, or revisions in informational materials or forms, to be used by investigators to obtain informed consent of human subjects and any additional informational materials, or revision in such informational materials, supplied to investigators, which had not been submitted in an application under § 813.20(b)(8) and (9) or any subsequent reports to the Food and Drug Administration. The sponsor shall submit such forms or materials to the Food and Drug Administration at the same time that they are provided to investigators.

§ 813.40 General.

The requirements of this subpart are applicable to sponsors of investigational studies, including sponsor-investigators.

§ 813.42 Review of the investigational study by the Food and Drug Administration and the institutional review committee.

(a) The sponsor shall submit for review and approval by the Food and Drug Administration an application for an investigational device exemption in accordance with Subpart B of this part before any human subjects are allowed to participate in the investigational study.

(b) The sponsor shall not permit any human subjects to participate in the study until the study has been approved by an institutional review committee and the application for exemption is approved by the Food and Drug Administration.

(c) The sponsor shall assure that the institutional review committee and the Food and Drug Administration are provided all the information on the proposed investigational study and the lens that they will need to review, approve, and monitor the study.

(d) The sponsor shall obtain from the institutional review committee a statement, signed by the chairman, that the committee has approved the investigational plan and has reviewed the report of prior investigations of the lens and that the committee will monitor the investigation in accordance with Subpart D of this part.

(e) The sponsor shall not implement a change in or deviate from the investigational plan, or permit a change or deviation to be implemented, unless there has been compliance with the requirements of §§ 813.39 and 813.105.

§ 813.43 Selection of investigators.

(a) The sponsor shall select as investigators only individuals who, because of their training or experience, qualify as suitable experts to investigate the safety and effectiveness of the lens. As a minimum, investigators shall have completed successfully a residency in ophthalmology or its documented equivalent and be licensed to practice medicine in the State or country in which the investigational study is to take place. Sponsors shall adopt appropriate additional criteria for investigators (bearing in mind the investigational plan, the report of prior investigations of the lens, and what is known about the lens).

(b) The sponsor shall obtain from each investigator who will participate in the investigational study a signed agreement for submission to the Food and Drug Administration that includes the following:

(1) A statement of the investigator's education and experience in sufficient detail to allow determination of the investigator's qualifications for investigating the lens. Such statement shall include specific experience with the intraocular lens to be investigated, including date, amount and description of experience, and the name of the institutions where the lens was investigated or used.

(2) An agreement to comply with the investigational plan and the requirements of Subparts E and G of this part and Part 50 of this chapter.

(3) An agreement that any use of the lens involving human subjects will be under the investigator's supervision or under the supervision of another investigator who is responsible to him and who is named by the investigator in a signed statement under paragraph (b)(5) of this section.

(4) A statement as to whether any investigational study or other research by such investigator has been discontinued on the order of a sponsor, an institutional review committee, or the Food and Drug Administration.

(5) The name of any other investigator who will participate in the investigator's supervision and responsible to him, with a statement of such other investigator's education and experience in accordance with paragraph (b)(1) of this section.

[42 FR 58889, Nov. 11, 1977, as amended at 47 FR 46079, Oct. 15, 1982]
§ 813.45 Control over the intraocular lens.

(a) The sponsor shall permit the lens to be shipped only to investigators who have signed statements under §813.43(b).

(b) If the study is suspended, terminated, completed, discontinued, or the exemption is withdrawn, the sponsor shall require the investigator to dispose of the lens in accordance with the requirements of §813.107(b).

(c) The sponsor shall assure that the methods, facilities, and controls selected for investigating and implanting the lens are adequate to assure the device will be tested under conditions that adequately assure the safety and effectiveness of the lens in the investigational study and, where the sponsor is a manufacturer, distributor, or importer of the lens, he shall also assure that the methods, facilities, and controls used for the manufacture, processing, and storage of the lens adequately assure the safety and effectiveness of the lens in the investigational study.

§ 813.46 Monitoring the investigational study.

(a) The sponsor shall designate one or more appropriately trained and qualified individuals to monitor the progress of the investigational study on a continuing basis and evaluate the data concerning the safety and effectiveness of the lens on behalf of the sponsor upon receipt of such data from investigators, and shall assure that such monitoring and evaluation occur.

(b) The sponsor shall review the investigational study periodically at intervals appropriate to the degree of risk to assure that the requirements of this part are met.

(c) Upon discovery by the sponsor that the investigator has not complied with the requirements of this subpart and Subpart G of this part or his agreement under §813.43(b), the sponsor shall secure the investigator’s compliance or discontinue shipments to the investigator and may require the investigator to return or otherwise make appropriate disposition of the lens in accordance with the requirements of §813.107(b), and may suspend or terminate any study being performed by the investigator for the sponsor.

(d) A sponsor shall not unduly prolong an investigational study. Where data are developed in the study that would support submission of an application for premarket approval of the lens pursuant to section 515 of the act, the sponsor shall either submit such an application or discontinue the study.

(e) Where the sponsor learns from an investigation and report of an adverse reaction under §813.153(b) that a serious adverse reaction is lens related and presents unreasonable risk to subject involved in the study he shall discontinue the study as soon as possible but in no event later than 5 days after sufficient information is available to warrant suspension. For purposes of this section, suspension of the investigational study means that no new subjects may be added to the study. Where the Food and Drug Administration regards an adverse reaction as lens related and as presenting unreasonable risk to subjects, the agency may request or order the sponsor to suspend the study and to take appropriate action to protect subjects in whom lenses have been implanted. The sponsor shall suspend the study and take such other action as soon as possible but in no event later than 5 days after such request or order. Once the study has been suspended, the sponsor shall not resume the study without the concurrence of the Food and Drug Administration.

§ 813.47 Submitting information to investigators.

(a) The sponsor shall supply all investigators with copies of the investigational plan required under §813.25, the report of prior investigations of the lens required under §813.27, and labeling (including labels) for the lens that describes all relevant hazards, contraindications, adverse reactions, interfering substances, precautions suggested by prior investigations, the sterility shelf life of the lens, and experience with the lens. The labeling shall not represent that the safety or effectiveness of the lens has been established for the purposes to be investigated.

(b) The sponsor shall notify each investigator of the completion or dis-
§ 813.50 Continuance of the investigational study or the withdrawal of the exemption as soon as possible but in no event later than 5 days after such action.

(c) The sponsor shall notify each investigator if an application for premarket approval of the device under section 515 of the act is approved.

§ 813.50 Promotion and sale of intraocular lenses.

(a) Neither the sponsor nor any person acting for or on behalf of the sponsor shall disseminate any promotional material representing that the lens being investigated is safe and effective for the purposes for which it is under investigation. This requirement does not restrict the full exchange of scientific information concerning the device, including dissemination of scientific findings. However, this requirement prohibits promotional claims by the sponsor that the lens is safe and effective while the device is being investigated to establish its safety and effectiveness.

(b) The sponsor of the study of an intraocular lens may distribute the lens only if the sponsor has an effective exemption under this part for all lenses sold, and all patients who receive a lens are included in an investigational study under an exemption.

Subpart D—Institutional Review Committee

§ 813.60 Requirement of institutional review committee.

An institutional review committee shall review and monitor all investigational studies of an intraocular lens, except that where an institutional review committee does not exist and one cannot be established, the sponsor of the study shall submit the investigational plan and report of prior investigations pursuant to §813.20(b) (5) and (6) for review by the Food and Drug Administration. The Food and Drug Administration may disapprove a study that is not to be reviewed and monitored by an institutional review committee if, in the opinion of the Commissioner, the lack of institutional review committee review may expose human subjects to undue risk.

§ 813.62 Membership of an institutional review committee.

(a) Any institutional review committee that undertakes to participate in the review of a proposed study shall possess the professional competence necessary to review the specific study. An institutional review committee shall be composed of not less than five individuals with varying backgrounds to assure complete and adequate review of the investigational study. Such committee shall include, in addition to persons possessing the professional competence necessary to review scientific activities, persons whose primary concerns are in nonscientific areas, e.g., lawyers, clergymen, ethicists, social scientists, or other lay persons. No such committee shall consist entirely of members of a single professional group.

(b) The records of a committee shall identify each member by name, earned degrees, positions or occupation, representative capacity, and other pertinent indications of experience, such as board certification or licenses, sufficient to describe each member’s chief anticipated contributions to such committee’s deliberations. The employment or other relationship between each member and the institution and any investigator or sponsor of any investigational study reviewed and monitored by the committee shall be described in the records of the committee, e.g., full-time employee, part-time employee, member of governing panel or board, paid consultant, or unpaid consultant.

(c) No committee shall consist entirely of persons who are officers, employees, or agents of, or are otherwise associated with, the institution, apart from their membership on the committee.

(d) No member of a committee shall participate in the committee’s review of monitoring of an investigational study in which he has a conflicting interest. No investigator or sponsor shall participate in the selection of members for a committee that will review his investigational study.

(e) The committee is responsible for determining whether a member has a conflict of interest and, if so, such
member shall not participate in the review or monitoring of the study.

(f) An institutional review committee may in its discretion invite persons with competence in particular areas (consultants) to assist in the review of complex issues whose resolution requires expertise beyond or in addition to that available within the committee. Consultants may not vote.

§ 813.65 Procedures for review and monitoring of investigational studies by an institutional review committee.

(a) An institutional review committee shall follow written procedures adopted by either the committee or the institution for conducting its review and monitoring of investigational studies and for reporting its findings to the institution, the sponsor, and the investigator.

(b) A committee shall conduct business by a quorum, which shall be defined by written procedures. In no event shall a quorum be less than a majority of the members of the committee.

(c) A committee participating in the review of an investigational study shall monitor that study until the investigation is completed or discontinued by the sponsor or terminated or suspended by the committee or an exemption is withdrawn by the Food and Drug Administration.

§ 813.66 Procedures and criteria for review of investigational studies by an institutional review committee.

(a) Upon receipt of the proposed investigational study, including an investigational plan and a report of prior investigations of the lens from the sponsor or investigator, a committee that is to participate in the review of the study shall perform the following functions:

(1) Determine that each investigator has successfully completed a residency in ophthalmology or its documented equivalent, and is licensed to practice medicine in the State or country in which the investigational study is to take place.

(2) Review the investigational plan and determine that the nature of the investigational study provides a benefit to the proposed subjects such that the risks to the subjects are justified.

(3) Assure that sufficient records will be kept so as to describe clearly the results of the study.

(4) Require the investigator to notify the institutional review committee of any unanticipated side effects or increased hazards, or any changes in the investigational study, actual or proposed, that have resulted or may result from the preliminary findings of the study that could result in modification or reversal of the initial determination to authorize beginning the study.

(5) Monitor the investigational study at intervals appropriate to the degree of risk but in no event exceeding 1 year so as to assure that the study continues to be justified during the course of the study.

(6) Assure that the rights of human subjects are properly protected, that legally effective informed consent is obtained, and that the method of obtaining consent properly informs the human subject of the significant aspects of the study in accordance with Part 50 of this chapter.

(7) Receive, process, and act on complaints relating to any study under review, e.g., from subjects, sponsor, and other members of an institution's staff.

(b) If the committee has any question regarding the proposed investigational study, the committee may request the investigator or sponsor to submit additional information concerning the proposed study.

(c) The committee shall review and approve, approve with modifications, or disapprove a proposed study as soon as possible after receipt thereof.

(d) The committee may disapprove a proposed study for any reason it considers appropriate and shall disapprove a proposed study if it makes any of the following findings:

(1) The information submitted to the committee concerning the study contains an untrue statement of a material fact or omits material information required by this part.

(2) The report of prior investigations of the lens is inadequate to support a conclusion that it is reasonably safe to begin the proposed investigational study.
§ 813.70

(3) There is reason to believe that the lens may be unsafe or ineffective when used for the purpose or in the manner for which it is to be investigated.

(4) The investigational plan is not a reasonable plan, in whole or in part, for a scientific investigation to determine whether the lens is safe or effective.

(5) The proposed investigational study does not conform to procedures, conditions, or requirements prescribed in this part.

(6) The investigator does not possess the scientific training and experience appropriate to qualify him as a suitable expert to investigate the safety and, where appropriate, effectiveness of the lens.

(7) The available clinical laboratory facilities and medical support are inadequate to assure that the study will be conducted properly and in conformity with the plan or to assure the safety of the subjects.

(e) A committee participating in the review may suspend or terminate a study after it has begun for any of the following reasons:

(1) Any reason for which the committee shall disapprove a study under paragraph (d) or (f) of this section.

(2) The investigator has disregarded committee recommendations for patient protection or has refused to cooperate with the committee, or to provide information to the committee.

(3) Experience developed during the study, or newly discovered scientific evidence not considered at the time the study was initially approved, indicates that the risks outweigh the potential benefits to the subjects.

(4) The investigator(s) who initiated the study cannot or will not continue to perform as an investigator, and a suitably qualified replacement is not available.

(5) There is evidence of fraud in the submission of data.

(6) The institutional support available for the study is no longer sufficient in quality or amount to assure the safe continuation of the study.

(7) There has been unethical conduct on the part of the investigator in the course of the study.

(8) Such other reasons as the committee may find appropriate.

In the event the committee terminates or suspends a study, it shall notify the sponsor and the Food and Drug Administration as expeditiously as possible, stating its reasons for the suspension, the duration of the suspension, the conditions, if any, under which the study will be permitted to continue, and its recommendations for the proper care of subjects.

(f) The committee shall disapprove a proposed study as being inadequate to justify commencement of testing involving human subjects if it determines that the proposed investigational study exposes the subjects to undue risks. In assessing risks, the committee shall consider, among other things, whether:

(1) The risks to the subject are so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks;

(2) The rights, safety, and welfare of any such subjects will be adequately protected;

(3) A legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of Part 50 of this chapter; and

(4) The conduct of the activity will be reviewed at timely intervals by the institutional review committee and the sponsor.

(g) The committee shall notify the sponsor or investigator who submitted the proposal of its decision on the proposed study. Notification of approval with modifications or of disapproval shall contain a statement of the reasons for the committee’s approval with modifications or disapproval.

[42 FR 58889, Nov. 11, 1977, as amended at 47 FR 40680, Oct. 15, 1982]

§ 813.70 Review by institution.

Approval, including approval with modifications, by an institutional review committee may be subject to further appropriate review and approval or rejection by institutional officials, but disapproval by the committee may not be overruled by such officials.
§ 813.79 Actions where review by an institutional review committee is inadequate.

(a) The Commissioner may determine that the process of review undertaken by an institutional review committee is inadequate if he finds that it failed to meet the requirements of this subpart or Subpart G of this part.

(b) If the commissioner finds that the process of review or monitoring undertaken by the committee is inadequate, he may:

(1) Request the committee to change it process of review or monitoring to meet the requirements of this subpart and Subpart G of this part;

(2) Require the sponsor to obtain review or monitoring by a committee whose process of review or monitoring meets such requirements;

(3) Require that the application be reviewed by the Food and Drug Administration; or

(4) Disapprove the application for an investigational device exemption or withdraw the exemption.

Subpart E—Investigator Responsibilities in Investigational Studies of Intraocular Lenses

§ 813.100 General.

The requirements of this subpart are applicable to investigators of investigational studies, including sponsor investigators.

§ 813.101 Review of investigational study by the Food and Drug Administration.

An investigator shall not allow human subjects to participate in an investigational study until such time as an investigational device exemption has been obtained from the Food and Drug Administration pursuant to Subpart B of this part.

§ 813.103 Review of investigational study by institutional review committee.

Where the investigation of an intraocular lens is subject to an institutional review requirement under §813.60:

(a) An investigator shall not allow human subjects to participate in an investigational study until the committee has approved the study.

(b) An investigator shall not implement a change in, or deviate from, the investigational plan until he has complied with the requirements of §813.105.

(c) An investigator shall report to the committee any serious adverse reaction occurring in the study that may reasonably be regarded as lens related and that was not previously expected in nature or severity or degree of incidence in the investigational plan.

(d) An investigator shall notify the committee within 3 months after completion or discontinuance of, or the withdrawal of the exemption for, the entire investigational study or of his portion of the study, whichever occurs first.

(e) An investigator shall provide accurate and adequate information regarding the investigational study to the committee in response to its request.

§ 813.105 Conformity to investigational plan.

(a) Whenever the investigator desires to implement a change in the investigational study that will result in a deviation from the investigational plan, he shall:

(1) Where such change may reasonably be expected to increase the risks to subjects and/or affect the scientific validity of the study under the criteria in §813.39(b), notify the sponsor of the proposed change and obtain the sponsor’s assent; submit, or assure that the sponsor submits, to the investigational review committee notice of such change and obtain the written approval of the investigational review committee; and submit, or assure that the sponsor submits, to the Food and Drug Administration a supplemental application in accordance with §813.39(b) and obtain the approval of the Food and Drug Administration before implementing the proposed change.

(2) Where such change may not reasonably be expected to increase the risks to the subjects, and does not affect the scientific validity of the study involved, the investigator may implement the change, but shall notify the sponsor and the institutional review committee.
§ 813.107 Control over intraocular lenses.

(a) An investigator shall only permit the lens to be used for administration to, or use involving, subjects who are under his personal supervision or under the supervision of another investigator who is responsible to him and who is named by the investigator in his signed statement undertaking the obligations of an investigator under § 813.43(b). An investigator shall not supply the lens to any other person for administration to, or use involving, subjects or for any other purpose, without the prior authorization of the sponsor.

(b) An investigator shall return to the sponsor any reusable or unused supply of the lens upon direction of the sponsor, or upon suspension, termination, completion, discontinuance of, or withdrawal of the exemption for, the investigational study. The sponsor may direct or agree to alternative disposition of the lens such as destruction or use in animal or in vitro experiments.

§ 813.119 Disqualification of a clinical investigator.

(a) Purposes. The purpose(s) of disqualification of an investigator who has violated the regulations set forth in this part may be one or both of the following:

(1) To preclude the investigator from conducting clinical investigations subject to requirements under the act for prior submission to the Food and Drug Administration until such time as it becomes likely that he will abide by such regulations or that such violations will not recur. The determination to disqualify an investigator does not necessarily constitute a finding or recommendation that the investigator is not qualified to practice or teach medicine or should be subject to other sanctions by other persons such as licensing boards or employers.

(2) To exclude the consideration of any clinical investigations or portions thereof in support of applications for an investigational exemption or for premarket approval from the Food and Drug Administration, which investigations have been conducted in whole or in part by the investigator, until such time as it becomes likely that he will abide by such regulations or that such violations will not recur or that it can be adequately demonstrated that such violations did not occur during or affect the validity or acceptability of a particular investigation or investigations. The determinations that a clinical investigation may not be considered in support of an application for exemption or premarket approval does not, however, relieve the applicant for such an application of any obligation under any other applicable regulation to submit the results of the investigation to the Food and Drug Administration.

(b) Grounds for disqualification. The Commissioner may disqualify an investigator upon finding all the following:

(1) The investigator violated any of the regulations set forth in this part;

(2) The violation or violations adversely affected the validity of the clinical investigation, the rights of the human subjects, and/or the safety of the subjects; and

(3) Other lesser regulatory actions, e.g., warnings or rejection of data from individual investigations, have not been or will probably not be adequate to assure that the investigator will comply with such regulations in the future.
(c) Notice of and opportunity for a hearing on proposed disqualification. (1) Whenever the commissioner has information indicating that grounds exist under paragraph (b) of this section that in his opinion may justify disqualification of an investigator, he may issue to the investigator a written notice proposing that the investigator be disqualified.

(2) A hearing on the disqualification of an investigator shall be conducted in accordance with the requirements for a regulatory hearing set forth in Part 16 of this chapter.

(d) Final order on disqualification. (1) If the Commissioner, after the regulatory hearing or after the time for requesting a hearing expires without a request being made, upon an evaluation of the administrative record of the disqualification proceeding, makes the findings required in paragraph (b) of this section, he shall issue a final order disqualifying the investigator. Such order shall include a statement of the basis for that determination and shall prescribe any actions (set forth in paragraph (e) of this section) to be taken with regard to ongoing regulated clinical investigations being conducted by the investigator. Upon issuing a final order, the commissioner shall notify the investigator and provide a copy of the order.

(e) Actions upon disqualification. (1) No clinical investigations subject to requirements for prior submission to the Food and Drug Administration will be authorized by the Food and Drug Administration if such investigation is to be conducted, in whole or part, by a disqualified investigator.

(2) The commissioner, after considering the nature of each ongoing clinical investigation that is being performed by the investigator and is subject to requirements for prior submission to the Food and Drug Administration, the number of subjects involved, the risks to them from suspension of the investigation, and the need for involvement of an acceptable investigator, may direct, in the final order disqualifying an investigator under paragraph (d)(1) of this section, that one or more of the following actions be taken with regard to each such investigation:

(i) The investigation may be terminated or suspended in its entirety until the investigator is reinstated under paragraph (k) of this section or another investigator accepts responsibility for the investigation.

(ii) No new subject shall be allowed to participate, or be requested to participate, in the investigation until the investigator is reinstated under paragraph (k) of this section, or another investigator accepts responsibility for the investigation.

(iii) Any human subject who has previously been allowed to participate in the investigation and who remains under the supervision of the investigator shall continue to be monitored by the investigator, but the human subject shall not receive another lens until the investigator is reinstated under paragraph (k) of this section or another investigator accepts responsibility for the investigational study.

(iv) Any human subject who has been allowed to participate in the investigation and who, except for suspension of the investigation, would have received the lens shall not receive it unless another investigator accepts responsibility for the investigation.

(f) Disqualified investigators and applications. Once an investigator has been disqualified, each application for an in-
vestigational exemption or for premarket approval, whether approved or not, containing or relying upon any clinical investigation performed by the investigator may be examined to determine whether the investigation was or would be essential to a regulatory decision regarding the application. If it is determined that the investigation was or would be essential, the Food and Drug Administration shall also determine whether the investigation was acceptable notwithstanding the disqualification of the investigator. Any investigation done by an investigator before or after disqualification may be presumed to be unacceptable, and the person relying on the investigation may be required to establish that the investigation was not affected by the circumstances that led to disqualification of the investigator, e.g., by submitting validating information. If the investigation is determined to be unacceptable, such investigation will be eliminated from consideration in support of the application, and such elimination may serve as new information justifying the termination or withdrawal of approval of the application.

(g) Clinical investigations begun by a disqualified investigator. No clinical investigation begun by an investigator after the date of his disqualification will be considered in support of any application for an exemption or premarket approval application unless the investigator has been reinstated under paragraph (k) of this section. The determination that a clinical investigation may not be considered in support of an application for an exemption or premarket approval application does not, however, relieve the applicant of any obligation under any other applicable regulation to submit the results of the investigation to the Food and Drug Administration.

(h) Public disclosure of information regarding disqualification. (1) Upon issuance of a final order disqualifying an investigator, the Commissioner may notify any other person known to have professional relations with the investigator (e.g., other Federal government departments or agencies that support investigations possibly involving the investigator, State and local medical licensing boards and societies where the investigator practices or is licensed, and administrators and institutional or peer review boards in universities, hospitals, and other institutions in which the investigator teaches or practices) that the investigator has been disqualified by the Food and Drug Administration. Such notice may be given in the discretion of the Commissioner whenever he believes that such disclosure would further the public interest or would promote compliance with the regulations set forth in this part. Such notice, if given, shall include a copy of the final order issued under paragraph (d) of this section and shall state that the disqualification constitutes a determination by the Food and Drug Administration that the investigator is not eligible to conduct clinical investigations subject to requirements for prior submission to the Food and Drug Administration and that the results of any clinical investigations conducted by the investigator may not be considered by the Food and Drug Administration in support of any application for an exemption or premarket approval application. The notice shall further state that it is given because of the professional relations between the investigator and the person notified and that the Food and Drug Administration is not advising or recommending that any action be taken by the person notified.

(2) A determination that an investigator has been disqualified and the administrative record regarding such determination are disclosable to the public under Part 20 of this chapter.

(3) Whenever the Commissioner has reason to believe that an investigator may be subject to disqualification, he may, in his discretion, so notify the sponsor of any ongoing clinical investigation in which that investigator is participating simultaneously with or subsequent to proposing disqualification of the investigator under paragraph (c) of this section, unless there are overriding safety considerations that warrant earlier notification of the sponsor.

(i) Alternative or additional actions to disqualification. Disqualification of an investigator under this subpart is independent of, and neither in lieu of nor a precondition to, other proceedings or
actions authorized by the act. The Food and Drug Administration may, at any time, institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action in addition to or in lieu of (and prior to, simultaneously with, or subsequent to) disqualification. The Food and Drug Administration may also refer pertinent matters to another Federal, State, or local law enforcement or regulatory agency for such action as that agency deems appropriate.

(j) Suspension or termination of an investigator by a sponsor. The sponsor of an investigational study may at any time remove an investigator from further participation in the study, whether or not the Food and Drug Administration has begun any action to disqualify the investigator. The sponsor need not use either the grounds or the procedures for disqualification set forth in this subpart. If a sponsor removes an investigator from a study, the sponsor shall notify the Food and Drug Administration in writing of the reasons for such removal as soon as possible, but in no event later than 5 days after such removal.

(k) Reinstatement of a disqualified investigator. An investigator who has been disqualified may be reinstated as eligible to conduct clinical investigations subject to requirements for prior submission to the Food and Drug Administration, or as acceptable to be the source of clinical investigations to be submitted to the Food and Drug Administration, if the Commissioner determines, upon an evaluation of a written submission from the investigator, that the investigator can adequately assure that he will conduct such studies in compliance with the requirements set forth in this part. A disqualified investigator who wishes to be so reinstated shall present in writing to the Commissioner reasons why he believes he should be reinstated; the investigator shall also submit a detailed description of the corrective actions he has taken or intends to take to assure that the acts or omissions that led to disqualification will not recur. The Commissioner may condition reinstatement upon the submission of an acceptable protocol for a specific clinical investigation providing for additional corrective actions and/or the submission of special undertakings by a sponsor, an institution, an institutional review committee, or another investigator to review in detail the investigator’s compliance with the requirements of this part and/or the investigator’s being found in compliance with the applicable regulations upon an inspection. If an investigator is reinstated, the Commissioner shall so notify the investigator and all organizations and all persons who were notified under paragraph (h) of this section of the disqualification of the investigator. A determination that an investigator has been reinstated is disclosable to the public under Part 20 of this chapter.

[42 FR 58889, Nov. 11, 1977, as amended at 53 FR 11253, Apr. 6, 1988]

Subpart F—[Reserved]

Subpart G—Inspections, Reports, and Records

§ 813.150 Inspections.

(a) Any sponsor, institutional review committee, or investigator shall permit an authorized employee of the Food and Drug Administration, at reasonable times and in a reasonable manner, to inspect and copy any records concerning the investigational study that are required to be kept by this part.

(b) Any sponsor or investigator who has authority to grant access to the facility shall also permit authorized FDA employees, at reasonable times and in a reasonable manner, to inspect any facilities where the intraocular lens is manufactured, processed, held, used, or implanted.

(c) Any investigator shall permit an authorized employee of the Food and Drug Administration to copy records that identify the names of human subjects, upon notice that the Food and Drug Administration has reason to believe that the consent of human subjects was not obtained, that reports submitted by the investigator to the sponsor or to the institutional review committee do not represent actual cases or actual results obtained, or that such reports or other required records

§ 813.150 Inspections.
§ 813.153 Reports.

(a) Recall reports. Any sponsor shall notify the Food and Drug Administration of any request that investigators return, or otherwise dispose of, any supplies of the intraocular lens, or examine any patients that previously received a lens.

(b) Adverse reaction reports. If during the study a seriously adverse reaction occurs that may reasonably be regarded as lens related and that was not previously expected in nature, severity, or degree of incidence in the investigational plan (including any incidence of hypopyon, intraocular infection, or acute corneal decompensation), the following actions shall be effected:

(1) The investigator shall investigate the reaction and submit an accurate and adequate report of the investigation to the sponsor and to the committee as soon as possible but in no event later than 5 days after learning of the reaction;

(2) The sponsor shall evaluate any adverse reaction report submitted by the investigator any reports received from other sources and within 5 days after learning of the adverse reaction, shall report the adverse reaction and the results of is evaluation to the Food and Drug Administration, any committee(s) monitoring the study, or part of the study, in which the reaction occurred (if the investigator(s) has not already reported the reaction to the committee(s)), and all other investigators and sponsors participating in the study. In the case of hypopyon, except where the Food and Drug Administration directs otherwise, a sponsor need only report the adverse reaction and results of his evaluation to other investigators and committees participating in the study where the incidence of the reaction exceeds that which was previously anticipated in materials provided to investigators.

(c) Progress reports. (1) Any investigator shall submit accurate progress reports to the investigational review committee and sponsor (or his monitor) at appropriate intervals but in no event at intervals exceeding 1 year.

(2) The sponsor shall make accurate and adequate progress reports to the Food and Drug Administration at appropriate intervals not exceeding 1 year. Such reports shall include any significant findings of the study and any necessary amendments or corrections to previous reports or to the application to keep them accurate.

(d) Suspension/termination reports. (1) Any investigator shall report to the sponsor any suspension or termination of the investigational study by a committee within 5 days.

(2) Any institutional review committee shall immediately report any suspension or termination of a study it is reviewing and monitoring under this part to the Food and Drug Administration.

(e) Final reports. (1) Within 3 months after the completion or discontinuance of or withdrawal of the exemption for the investigational study (or the investigator’s portion of the study), any investigator shall notify the committee and sponsor and make an accurate and adequate final report to the sponsor, and the final report shall include all reports not previously submitted to the sponsor but required by paragraphs (b), (c), or (d) of this section.

(2) Within 30 days after the completion or discontinuance of a study or the suspension or termination of a study by a committee, the sponsor shall notify the Food and Drug Administration of the action.

(3) Within 6 months after the study is completed, discontinued, suspended, or terminated or the exemption is withdrawn, the sponsor shall make a final report to the Food and Drug Administration.

§ 813.155 Records.

(a) The sponsor, any investigator, and any committee shall maintain adequate and accurate records concerning the investigational study, including copies of all correspondence, among themselves and with the Food and Drug Administration regarding the study.

(b)(1) The sponsor and any investigator shall maintain adequate and accurate records showing the shipment, re-
Subpart H—Investigational Studies That Do Not Involve Human Subjects

§ 813.160 Conditions of exemption.

(a) Where an investigational device is intended for use in humans, a shipment of the device that is intended solely for

cept, or other disposition of all supplies of all lenses shipped or received.

(2) The sponsor either shall provide

to each investigator an identification

card that is to be provided to each sub-

ject after implantation or shall provide

each subject with such a card. The card

shall include the following information

on each lens: Lens name, manufactur-

er’s name and address, model number,

style and serial, batch, lot, or other

identification number for each lens.

The sponsor and each investigator

shall maintain the following records:

identification by name of the inves-

tigator who received each unit of the

lens and who administered the device;

the identification by code of the sub-

ject who received it; and identification

of each unit otherwise disposed of (in-

cluding identification of the person

who disposed of it, the person, if any,

who received it, and the purpose or rea-

son for its disposal, e.g., because of

contamination or return to the spon-

sor).

(c) An institutional review commit-

tee shall prepare and maintain ade-

quate documentation of its activities

regarding each investigational study,

including records of information sub-

mitted to the committee by sponsors

or investigators, information compiled

on committee members pursuant to

§813.62, minutes of committee meetings

on issues involved in the study and

their resolution, committee decisions

on the study, and dated reports of suc-

cessive monitoring as it is performed.

(d) Contents of investigator records.

An investigator shall maintain an ade-

quate and accurate case report on each

subject, which shall include the follow-

ning:

(1) All relevant observations, infor-

mation, and data on the condition of

the subject at the time the subject en-

ters into the study, including informa-

tion regarding any relevant previous

medical history and the results of all

diagnostic tests performed to deter-

mine that the subject is appropriate for

entry into the study.

(2) All documentation regarding the

consent of the human subjects, as re-

quired by Part 50 of this chapter.

(3) All relevant observations and data

on the condition of the subject

throughout the duration of his partici-

pation in the study.

(e) The sponsor shall retain a copy of

any application, report, or correpond-

ence that he submits to the Food and

Drug Administration under this part.

(f) A sponsor, investigator, and insti-

tutional review committee shall main-

tain records required under this part

for whichever of the following periods

is shortest:

(1) A period of 2 years after the date

on which the Food and Drug Adminis-

tration approves the marketing of the

lens for the purposes that were the sub-

ject of the study.

(2) A period of 5 years after the date

on which the results of the study are

submitted to the Food and Drug Ad-

ministration in support of the market-

ing of the lens for the purpose that was

the subject of the study.

(3) In other situations, e.g., where the

investigational study does not result in

the submission of an application for

marketing the device for the purposes

that were the subject of the study, a

period of 2 years after the date on

which the investigational study (not

merely an investigator’s portion of a

study) is terminated, completed or dis-

continued, or the exemption is with-

drawn.

(g) A Sponsor, investigator, or com-

mittee may withdraw from the respon-

sibility for maintaining records for the

period of time required in paragraph (f)

of this section by transferring custody

to any other person who will accept re-

ponsibility for the records. Notice of

such transfer shall be given to the

Food and Drug Administration.

(h) The Food and Drug Administra-

tion may require a sponsor to submit

any records concerning the investiga-

tional study, including any records re-

quired to be kept under this part.

[42 FR 58899, Nov. 11, 1977; 43 FR 1940, Jan. 13,

1978, as amended at 47 FR 46080, Oct. 15, 1982]
§ 813.170 Termination of exemption.

(a) The commissioner shall terminate an exemption under this subpart if he makes either of the following findings:

(1) The person shipping an investigational device under this subpart has failed to comply with any of the conditions for the exemption under this subpart.

(2) Any of the grounds for withdrawal of an investigational device exemption under §813.35 apply.

(b) The Commissioner shall notify the sponsor of the termination of an exemption under this subpart with a full statement of the reasons for such termination and shall afford an opportunity for a regulatory hearing under Part 16 of this chapter. The person whose exemption is terminated shall recall or otherwise assure the destruction of any unused devices.

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

Subpart A—General

Sec.
814.1 Scope.
814.2 Purpose.
814.3 Definitions.
814.9 Confidentiality of data and information in a premarket approval application (PMA) file.
814.15 Research conducted outside the United States.
814.17 Service of orders.
814.19 Product development protocol (PDP).

Subpart B—Premarket Approval Application (PMA)

814.20 Application.
814.37 PMA amendments and resubmitted PMA's.
814.39 PMA supplements.

Subpart C—FDA Action on a PMA

814.40 Time frames for reviewing a PMA.
814.42 Filing a PMA.
814.44 Procedures for review of a PMA.
814.45 Denial of approval of a PMA.
814.46 Withdrawal of approval of a PMA.

Subpart D—Administrative Review

Subpart E—Postapproval Requirements

814.80 General.
814.82 Postapproval requirements.
814.84 Reports.


Source: 51 FR 23654, July 22, 1986, unless otherwise noted.